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OVERSIGHT OF IMPLEMENTATION OF THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1988

JOINT HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

AND

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

EXAMINING THE STATUS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IMPLEMENTATION OF THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988, TO REQUIRE ALL MEDICAL LABORATORIES PERFORMING TESTS IN THE UNITED STATES TO MEET CERTIFICATION REQUIREMENTS

MARCH 9, 1990

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OVERSIGHT OF IMPLEMENTATION OF THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1988

FRIDAY, MARCH 9, 1990

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES, AND
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT
MANAGEMENT, OF THE COMMITTEE ON GOVERNMENTAL
AFFAIRS,
Washington, DC.

The Joint Hearing convened, pursuant to notice, at 10:10 a.m., in room SD-430, Dirksen Senate Office Building, Senator Brock Adams, presiding.

Present: Senators Adams, Mikulski, Levin, and Cohen.

OPENING STATEMENT OF SENATOR ADAMS

Senator ADAMS. The Joint Hearing of the Committee on Labor and Human Resources and the Committee on Governmental Affairs, Subcommittee on Oversight of Government Management, on the Oversight of the Implementation of the Clinical Laboratory Improvement Act of 1988 will come to order.

Two years ago, I sat in this room and heard testimony from a constituent of mine who told the committee how she received two negative Pap tests from two different laboratories just prior to discovering that she had cervical cancer.

At that hearing, I made a commitment to my constituent and to myself to pursue legislation to establish Federal regulations which would help prevent a recurrence of this tragedy.

Senator Mikulski and I spent a great deal of time in the Committee on Labor and Human Resources on this problem, and members of the other committees have conducted oversight on this matter.

Out of that hearing came enactment of the Clinical Laboratory Improvement Amendments of 1988. When President Reagan signed this law on October 31, 1988, we expected that by January 1st of this year Americans like my constituent would be reassured by implementation of Federal regulations to improve the quality of our Nation's laboratories.

But January 1st has come and gone, and still we have not even seen proposed regulations from the Department of Health and Human Services to implement this congressional mandate.

In the meantime, the quality in our Nation's laboratories still leaves much to be desired. We in Congress did not act on this bill

and the President did not sign this bill because we thought it was a nice thing to do. We acted because preventable mistakes in our Nation's medical laboratories result in unnecessary or premature death. People have died and continue to die because there is poor quality control in many of our Nation's medical laboratories. We in Congress expected—and still expect—you at the department to take this appalling situation seriously and act as you are required to do by law.

Testimony we will hear later during this hearing regarding a survey of 18 cytology labs around the country resulted in findings of critical deficiencies in eight of those laboratories and disturbing shortcomings in the remainder surveyed.

Clearly, these deficiencies will not go away without Federal regulation. The case for timely implementation of CLIA 1988 is a sound one. Each month the implementation of this bill is delayed, more cancers go undetected; more men and women receive erroneous laboratory reports, and more tragedies result. In a time when we must increasingly rely on accurate laboratory results to control serious new threats to public health like AIDS, it is essential that our laboratory test results be accurate and timely.

Currently, Federal regulation under CLIA 1967 only affects about 12,000 of the more than 100,000 laboratories in the United States. It is critical that all laboratories be regulated. I know that it is not simple to devise a new regulatory scheme. This is admittedly a complex task for Federal regulators.

At the same time, it is essential that it get the priority attention that it deserves, that Congress intended that it have. There is really no acceptable rationale for the fact that since the enact of CLIA 1988 we do not have proposed regulations on the street for public comment—and that we are not at least heading toward finalization of these regulations in the near future.

As we move forward here today, I want to know from Administrator Wilensky when we can expect final regulations to implement CLIA, when they will be in effect. Congress has done its job. We recognized a deficiency in our medical regulation, developed a consensus on policy, and acted to bring that into law. The ball is in your court. It is now time for you to act without further delay.

I am particularly pleased to be here with my colleague and joint Senate sponsor of the Clinical Laboratory Improvement Amendments, Senator Mikulski. I am also pleased that we are able to hold this hearing jointly with the Oversight Subcommittee of Government Affairs. Senator Cohen and Senator Levin have both worked hard on this issue over many, many years. We appreciate their efforts, and we appreciate very much your being with us this morning. They have contributed much to this debate and much to the legislative solution.

We look forward to the testimony of the various witnesses this morning, but prior to that, I would like to turn first to my colleague Senator Mikulski and then to my colleagues Senator Levin and Senator Cohen for any opening statements that they may wish to make.

Senator Mikulski.

Senator MIKULSKI. Thank you very much, Senator Adams.

This is a melancholy hearing—melancholy because it was in October of 1988 that we passed a law which we hoped would save thousands of lives by having accurate laboratory testing. The law has been passed, and the law has not been implemented.

The implications of that is that there are people at risk because of the failure to implement a government policy. I had hoped that by now the United States Government through its clinical lab regulatory framework would have had the results out there to say to the people that finally, you can trust your laboratories—Pap smears, cholesterol, all of those things that we rely on.

I would hope that no one would ever have to go through the heart-wrenching situation that my constituents, Jeff Miller and his wife, in my own State of Maryland went through. Jeff watched his wife, his high school sweetheart, the mother of two boys, die of cancer because of the way it was mishandled—not once, but twice—in a Maryland clinical lab. This was a woman who took care of herself in the same way she tried to take care of her family. She went and had her Pap smear and then, through mishandling, an inflammation report was missed; back again and again, mishandled again.

Sadly—this continues to be a pattern throughout this country. The truth is, women are just as likely to die from misread Pap smears today than they were 2 years ago when we passed the law. Victims of AIDS may be unaware that they are carrying the virus, and people with dangerously high cholesterol levels may go untreated.

As a United States Senator, I want to save lives. My sworn duty is to protect people from risk. I took a Constitutional oath to protect American citizens from all enemies, foreign and domestic. The domestic enemy is disease, and one of the ways we protect them from disease is through laboratory testing.

Now I find I've got to hold this hearing not only to protect my constituents from disease, but from the glacial, sluggish progress of implementing government policy. Mr. Chairman, that is unacceptable.

Six thousand women die each year from cervical cancer. That is not a number. That is 6,000 families—husbands, children who are now orphans because of, again, botched up procedures.

I don't know how many of these women died because their cancer was misdiagnosed early on, but in many cases errors were not caught. But I do know that even one women dying because of a laboratory error rate is terrible; one woman dying because the Federal law was not implemented is inexcusable.

Now, why are we in this situation? Because the Health Care Financing Administration has let us down. They didn't do the job the way they should. And today we want to find out what are they going to do about it to make sure that these clinical lab regulations, that were designed for safety and protection, are designed, implemented, and workable.

Now, I know that HCFA has a tough job, and I know that they have been squeezed with their work force. HCFA is in my own State of Maryland, lots of dedicated people. But I will tell you, it is not the ordinary people who worked on this that I bring into question. It is the topsiders—the topsiders who made a decision on how

they were going to do it. They are going to tell us that 16 months was not enough. Mr. Chairman, we've been in this for 5 years. I served on the Energy and Commerce Committee with our honorable colleague, Ron Wyden, and in 1985, we raised this issue back over there on Energy and Commerce, and we passed a law telling HCFA to report on minimum standards for office labs. That report was never issued.

In 1987, we passed a law asking HCFA to regulate the labs performing more than 5,000 tests. That was the physicians' labs again. No standards were ever developed. Then, in March of 1988, 2 years ago, HCFA testified that they had been looking at test complexity issues when they talked to Senator Levin and Senator Cohen, again, who had been working on this legislation.

Yet even after 5 years of us passing laws and holdings meeting, we have no scheme for regulating these labs. In the meantime, we have horror story upon horror story—secretaries interpreting tests, doctors' spouses filling in as lab technicians. What do we have to do to get HCFA to take the regulations of doctors' offices seriously?

Mr. Chairman, I could give you many more examples of how HCFA testified, again, in March 1988 about how intermediate sanctions were going to be published—well, we can't find them. Hearing provisions were going to be drafted in 1986; they were never published. Where are they? We can't find them. They were never published.

Now, we have a very able head of HCFA, Dr. Wilensky. I hear from everyone in the field of public health and public health care financing what a fine and competent person she is. We look forward to her picking up on essentially what has been the glacial, sluggish nature of these regs and also the fact that they decided to pursue their own so-called August 5th reg rather than the law that we implemented.

Mr. Chairman and my colleagues, I know that you are disappointed as I am. I would hope that this hearing would not only get the record straight, but get HCFA on the right track, and communicate that we need a sense of urgency.

Let me conclude by saying this, Mr. Chairman. When we sat here a couple of years ago and held our hearing, I asked one of the leading physicians in this country what shall we tell consumers; how can consumers protect themselves? And he said, "Well, when the women go to see their doctor, they should ask him how reliable the lab is."

I said to him, "Doctor, when I get on an airplane, I don't have to check my own sparkplugs. As a woman consumer, I don't think I have to check my own lab." And that's the kind of safety and protection we want. We want sparkplugs working in airlines, and we want lab regulations working in America's clinical labs.

I want to thank you, the other fine men from Government Affairs, my old pal from Energy and Commerce. You really are the Galahads, and I look forward to working with you.

Senator ADAMS. Thank you, Senator Mikulski. Thank you very much.

Senator Levin, welcome. We are very pleased that you are here this morning. You have spent a great deal of time and effort, and the country owes you a lot. We look forward to hearing from you.

Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

As you indicated, the Senate Subcommittee on Oversight of Government Management, which I chair, held hearings on HCFA's Management of Medical Laboratories in March of 1988. These hearings were held because Senator Cohen brought his great concern over the quality of medical lab testing in this country to the attention of our subcommittee.

He and his staff were instrumental in uncovering the kinds of shoddy lab testing which led to the tragedies which we have heard described this morning—the untimely death, for instance, of a young mother due to cervical cancer and the shattered hopes of a young couple who were led to believe by a faulty test that their unborn child would be free of the severely incapacitating and ultimately fatal Tay-Sachs syndrome.

The lab testing legislation which is the subject of today's hearing was designed to put teeth back into the laws covering medical labs. It brought virtually all medical labs under one unified regulatory program.

Senator Adams and Senator Mikulski were instrumental in getting that legislation passed in the Senate. The entire country owes them and Senator Cohen a debt of gratitude for their leadership in this area.

At the time that we passed the law, we all made statements promising that this new law would put accountability and reliability back into medical lab testing systems. Individuals would be able to go to their family doctor or hospital or an unfamiliar out-of-State medical facility and be able to expect the same high quality of testing procedures and personnel.

I am deeply troubled, as all of us are on this panel, that so much time and effort could be devoted to the investigation and subsequent strengthening of our Nation's Federal regulation of medical labs only to find ourselves facing a lengthy delay in the implementation of that law.

It appears that the Administration has dropped the ball on this issue. This hearing gives us an opportunity to find out why.

Thank you, Mr. Chairman.

Senator ADAMS. Thank you very much, Senator Levin.

Senator Cohen, your work in this has been outstanding, and as Senator Levin said, the country owes you a great deal of gratitude for first bringing it to our attention many years ago.

Senator COHEN.

Senator COHEN. Thank you very much, Senator Adams, Senator Mikulski and Senator Levin.

I would reiterate what Senator Levin said, that this is not the work of one individual. Congressman Wyden has been involved in the House. There are a lot of people who certainly share responsibility for moving the legislation and who deserve the credit.

I was interested in your statement, Senator Adams. You point out, for example, the very heart-rending case of one woman who had two tests misread and died of cervical cancer. Senator Mikulski had a similar situation. In the Oversight subcommittee, we had testimony along the same lines. But it should be pointed out it is not just a case where mistakes are made and someone loses his or

her life. The opposite is sometimes true, as well, where you have people who are put on expensive medical equipment, enduring months of medical treatment—unnecessary treatment—huge medical bills, anguish and fear of what might take place.

We had one gentleman from Virginia, a 65 year-old man who underwent four separate tests, all of which were wrong, resulting in his being put on kidney dialysis. An extraordinary amount of bills that were incurred, many, many trips to the doctor's office, and the fear of what his life was going to be like. So it cuts both ways, not only that something may go undetected, but that something may be detected that is not there. That also produces an anomalous situation.

Also what I think is important to recognize from the opening statements is that this goes well beyond Pap smears. That is terribly important. Errors in Pap smears is not the only problem we have. We have problems in the accuracy of AIDS testing, or in cholesterol testing. This week in *Time* magazine, there was a little item summarizing what the Department of Health and Human Services' Inspector General just revealed. He found that not only is not all well in lab testing, but that there is considerable laxity of quality assurance and disregard of even basic hygiene at public cholesterol screenings, such as screening at malls and health fairs. We have thousands of people going to these malls and health fairs, and we are finding that there is almost a total lack of quality control in what is being done at those malls.

When we talk about Pap smearing, Pap mills, there is estimated to be anywhere from a 20 to 40 percent error rate, which is shocking. *Time* magazine suggests that when you go to one of these malls for your cholesterol tests, perhaps the best thing to do is to go and get a second opinion. The problem is that a second opinion might not be any good, either, or a third opinion, as long as we don't have in place the kind of comprehensive quality control, proficiency testing, and personnel who are qualified to carry out these types of tests.

One other point, and that is all of us up here know, and many in the room, that if you are a lawyer and you make a mistake, you can always appeal the case; if the court makes a mistake, you can appeal the case. If you are a Senator or a Congressman and you make a mistake, you can always ask to amend the statute. If you make a mistake in lab testing, the consequences may be irreversible. We may end up burying that mistake with the patient.

So I would like to join my colleagues in emphasizing the sense of urgency that all of us feel because there is some notion, perhaps, on the part of the public that because we go along passing laws, that somehow their lives are made safer, and that's not the case. They are not any safer as a result of the CLIA 1988 Amendments having been passed, and I think it is important that we emphasize the sense of urgency that when we pass laws that we do proceed with every element of speed that we can, given the complexity of the law that is involved, and try to implement the intent of Congress to carry out our duty to protect the citizens.

Thank you very much.

Senator ADAMS. Thank you, Senator Cohen.

Senator ADAMS. It gives me a great deal of pleasure to welcome on behalf of both committees our colleague from the House, who has had a long interest in this and is also an old friend from a neighboring State.

Ron, we are very pleased that you can be here this morning, and we look forward to your testimony.

The honorable Ron Wyden, from the State of Oregon.

STATEMENT OF THE HONORABLE RON WYDEN, MEMBER OF CONGRESS, STATE OF OREGON

Mr. WYDEN. Thank you very much, Mr. Chairman.

With your permission, perhaps I could just put my prepared remarks in the record and maybe just make a few comments today. I won't give you a big filibuster or anything.

Senator ADAMS. Without objection, your statement will appear in full in the record as though given.

Mr. WYDEN. Thank you very much, Mr. Chairman.

First of all, just listening to you four, one is compelled to say "Hooray" and walk out, because I think you all have said it very well, and it really has been a pleasure to join with you over these last few years in a bipartisan effort to try to turn this around.

As Senator Mikulski has said, we have been working on this for years and years, and I would just make a few substantive points I think today that address the research that we have been doing into the current situation.

As the members have said, Gail Wilensky is new at the Health Care Financing Administration, and we are all very encouraged that she has taken over, and her people have reached out to us, just like you all as well, to indicate that they are going to work with us.

But the fact of the matter is that for several years now, the Health Care Financing Administration has been diddling while Americans are being injured as a result of shoddy medical testing. And I am of the view that the strategy of the Health Care Financing Administration for all these years has been to do just enough to avoid having a Congressional oversight hearing, where everybody brings them in and says, "Why aren't you moving?"

Again and again and again, we have been trying to get this agency to push the issue of questionable medical testing to the front of the burner, and again and again they have found one reason or another to push it back and to find another reason for delay and holding off.

I thought what I'd do is talk about five points today that specifically concern me about the way they are going about this task.

First, in spite of the fact we have been at this for years now, the Health Care Financing Administration hasn't even done the basic research to find out how many labs are out there and what kinds of tests they are actually doing.

For example, along with many of you, I have been interested in what is the explosive area of medical testing, which are physician office labs and mobile testing. Several years ago, we were told by the Inspector General—2 years ago, my subcommittee was told—

there were about 100,000 unregulated, uninspected physician office labs, and they do about 25 percent of all the testing.

What we have been told by the Health Care Financing Administration, however, is that they are now using 300,000 to 600,000 as the standard for the number of physician office labs. We have no idea where these labs are. We don't even know where they came up with these numbers. But it seems to me that if you are going to make a dramatic departure from what the Inspector General has said in terms of the fastest growing area of medical testing, you ought to have to have some kind of factual basis for doing it.

The second point that concerns me, Mr. Chairman and colleagues, is that I think that the Health Care Financing Administration, on the basis of what we have seen so far, looks like it is just going to exempt a great number of the really important medical tests, under an exemption that we said ought to be interpreted very narrowly. In the CLIA legislation we said that, yes, there could be a waiver if one of the tests posed an "insignificant risk of public harm". But what they have done with their regulatory wand is take this list so it now includes tests for sickle cell anemia, blood clotting, strep, and gonorrhea, basically exempting tests that would give physicians and their patients early warning signals of liver and kidney disease, rheumatic fever, and countless infections.

I am very concerned that on the basis of what we know at this point, again, they are going off the regulatory boat, taking an area that we thought should be interpreted narrowly, and in effect saying that they are going to exempt a lot of these tests as simple. And I think because you all have studied this issue, you know that if one of our constituents gets hurt, they are not going to be interested in some philosophical discussion with the Health Care Financing Administration. They are going to say why weren't there some rules over these tests.

And Senator Cohen, we held a hearing on the cholesterol issue some months ago, and I am just hopeful that the Health Care Financing Administration won't exempt those cholesterol tests as simple, because what we found was just scandalous. I mean, we found people without any qualifications; we found people's fingers being squeezed or milked, which tainted the testing; and yet, under what we have learned about the way HCFA is going about this task, they would just use the simple test exemption and gut an awful lot of what we wanted to do in the 1988 bill.

The third point that I want to mention, Mr. Chairman, is that despite our concerns in CLIA over the laxity of existing accrediting bodies for these labs, and the directions to HCFA to develop standards and to evaluate the performance, everything that we have seen indicates that HCFA is ignoring the mandate with respect to toughening standards on accrediting bodies for the labs.

Fourth, and a very important point, the Health Care Financing Administration has still not established an efficient civil or criminal process to close down a dangerous lab. They are talking about this convoluted process of getting an injunction. But what we really need is a convenient, direct, quick way to really go after a dangerous lab.

The last point that I want to mention in terms of how I think they are leaving behind what we intended deals with the question

of AIDS. What we have seen indicates that they really are giving this test short shrift. In 1987 there were reports of 90 percent false positives and 10 percent false negatives among the low-risk populations, but what they have been discussing does in no way address issues of counseling, confirmatory testing, or special standards for AIDS testing. And this is in spite of a warning from the Public Health Service that these standards are key to ensuring reliable HIV testing.

So those are five specific areas, Mr. Chairman and colleagues, where what we have seen the Health Care Financing Administration doing simply departs from what we had in mind in CLIA 1988.

Now, they are coming, and they've got this big regulation, with hundreds of pages in it and the like. But that is a reimbursement regulation; that doesn't deal with what I think our constituents are most concerned about, which are quality controls. That is what they want. Senator Mikulski was saying that when you go into one of these places, the citizens expect that somebody is watching and somebody is monitoring, and the regulation we are getting today simply doesn't deal with it.

So what I would say as my last point, Mr. Chairman, is I think we need to have the Health Care Financing Administration immediately move to some interim regulations in the area of quality controls. We can't allow this to be dragged out for another two or 3 years. They are going to, as in areas of physician office labs, say there are many more than the Inspector General was talking about and the like. And I am concerned that they will just drag this on and on.

I would like to work with you and our colleagues that are interested in it—as you know, Chairman Dingell is very interested on the House side—to get HCFA to adopt some immediate interim quality controls to deal with these dangerous issues that we have been talking about.

That will be the end of my orating. I appreciate the chance to comment.

[The prepared statement of Mr. Wyden follows:]

PREPARED STATEMENT OF MR. WYDEN

At the outset, let me thank you for inviting me to testify today. I know that we share a common concern about dangerously inaccurate medical testing.

I agree with everything you've just said. The Clinical Laboratory Improvement Amendments of 1988 is a textbook case of the legislative process at its best—it's one of our successes.

In 1988, we identified a serious public health risk and we took bipartisan action to eliminate it. Despite departmental resistance and strong pressure from many in the medical community, we acted to guarantee what our constituents should have expected all along—safe, reliable medical testing.

Our message was loud and clear, but something got lost as our landmark legislation made the short trip from Capitol Hill to HCFA's offices. Not only are the proposed regs overdue, but the drafts we've seen appear to depart dramatically and dangerously from clear Congressional intent. I'd like to address three key areas where I think HCFA has missed the boat.

We told HCFA that all labs had to be inspected and certified by the government unless the tests they performed posed "an insignificant risk" to patients even if they were inaccurately done, that regardless of how the test was performed the risk would be so small as to be without meaning.

With a cavalier wave of its regulatory wand, HCFA would exempt de facto virtually all physician office labs and mobile labs—probably the fastest growing segments

of the lab industry. HCFA's creative slight of hand distorts beyond all reason the CLIA 88 provision to waive tests that pose an insignificant risk of public harm. Even HCFA's sister agencies—CDC and FDA—have said that there is no such thing as a test without risk when done inaccurately.

Let's be clear: HCFA's exempt list includes such tests as those for sickle cell anemia, blood clotting, strep and gonorrhea. It exempts tests that give physicians and their patients early warning signals of liver and kidney disease, rheumatic fever and countless infections.

The reality of HCFA's plan would be not knowing where billions of tests are done, who does them and how safely and accurately they're done. In reality, HCFA tells the public that they're on their own.

I don't believe that HCFA can justify that position and I don't believe that we can accept it, in good conscience. If these tests are insignificant, if the results are meaningless, why are we doling out millions of dollars for them in this time of scarce health care dollars? Either they're worth paying for or they're not. Either they're important diagnostic tools or they're not. HCFA can't have it both ways.

With HCFA's exempt list, tens of thousands of labs stay unregulated and our constituents stay unprotected.

HCFA's draft also ignores the crucial importance of accurate and reliable AIDS testing to prevent the spread of this deadly disease. Despite reports of 90 percent false positive and 10 percent false negative test results among low risk populations in 1987, HCFA proposes no system to address counseling, confirmatory testing, or special standards for AIDS testing. this, too, is despite warnings from the Public Health Service that those standards are key to ensure reliable HIV testing.

Admittedly, we gave HCFA a tremendous challenge. It must increase its regulatory responsibilities 10 fold in only 15 months. I would like to believe that they've done their best to try and meet that challenge. But if HCFA's proposed lab regs bear any resemblance to the drafts we've seen, they will have violated both the letter and the spirit of that law. They will have put thousands of consumers at risk.

Even more important, HCFA will have failed to remove a clear threat to the public health from inaccurate and unsafe laboratory tests.

HCFA hasn't even done basic research to find out how many labs are out there and what kind of testing they're doing. For example, the I.G. told my subcommittee two years ago that there were some 100,000 unregulated, uninspected physician office labs doing approximately 25 percent of all testing. HCFA says the total number of labs they may have to regulate under CLIA 88 is somewhere from 300,000 to 600,000. What and where are those labs and where did the numbers come from?

Americans spent $5 billion for tests done in physician office labs in 1987 alone, according to the I.G. Of that, over $400 million was paid for by Medicare. According to the College of American Pathologists, 50 percent of all medical testing may now be done in physician office labs—so the price tag may be between $10 and $15 billion annually.

The other growth industry in lab testing is mobile labs—testing done at shopping malls, grocery stores and drug stores. But we don't have reliable and safe tests, there, either. Fully 25 percent of the cholesterol screening examined in four detailed case studies in Minnesota were inaccurate—specifically falsely low. So, people screened at those sites could unwittingly continue along potentially dangerous paths of poor diet and too little exercise subjecting them to greater risk of heart disease.

The government has urged us to practice preventive medicine, to know our cholesterol numbers, to know and control our blood pressure, to follow nutritionally sound diets, to start exercise programs, and to have PAP smears and mamographies that can improve our health both short- and long-term. Preventive medicine is the best and cheapest medicine. But under our current system we may be thwarting the best intentions of consumers and health care professionais.

Over two years ago, government analysts testifying before my subcommittee said that 9 out of 10 AIDS tests among low risk populations would yield false positive results. And they found that 10 percent of the tests done among low risk people would miss HIV positive individuals. But HCFA's draft doesn't even require physician review, confirmatory testing and counseling for AIDS testing.

The human suffering from the AIDS crisis is incalculable, but in stark financial terms, the price tag for AIDS treatment will be as high as $3 billion in the military alone over the next 10 years, according to a just-released General Accounting Office study requested by my subcommittee.

Despite Congress' concerns over laxity of existing accrediting bodies for these labs, and its direction to HCFA to develop standards to evaluate their performance, the HCFA draft also ignores this mandate.

And finally, Mr. Chairman, HCFA still has not establish either an efficient civil or criminal process to close down the most dangerous lab operations.

I want to work with you, my House colleagues, Administrator Wilensky, state regulators, and consumers and lab experts to act now to put in place interim measures that improve the quality of lab testing. We should require all labs to register with HCFA. We should require all labs to utilize minimum training, consistent with the complexity of the tests being done. And we should require proficiency testing, again consistent with the complexity of the tests performed.

We've held numerous investigative and legislative hearings, we've commissioned studies and we've passed a law to revamp our entire lab regulation system. But we still have nothing to show for those efforts.

Perhaps HCFA should heed the Biblical admonition, "Be yet a doer and not just a hearer of the word. Our constituents demand faithful doers in the protection of the public health—and they demand it now.

Thank you.

Senator ADAMS. Thank you very much, Congressman Wyden, for not only your excellent remarks, but for an outline of some of the specific things that can and should be done.

I have no questions. If the other members of the panel have no questions——

Senator LEVIN. I'll just State appreciation to you and to John Dingell and your colleagues for your work in the House. It is good work.

Mr. WYDEN. We'll be working with all four of you. Thank you.

Senator MIKULSKI. Thank you. It is good to see you again.

Senator ADAMS. Thank you very much, Congressman Wyden.

Panel 2 is Gail Wilensky, administrator of the Health Care Financing Administration.

What the chair proposes to do since this is a joint hearing is to start the questioning with Senator Levin, Senator Cohen, and then Senator Mikulski and I will question. And I would like to use a 5-minute time limit so that we can rotate through, and each one will have a chance to question. We'll go as many rounds as is necessary to obtain all the information that is required.

Administrator Wilensky, the committee welcomes you and looks forward to hearing your testimony. We will not put a time limit on your testimony.

STATEMENT OF DR. GAIL R. WILENSKY, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, WASHINGTON, DC.

Dr. WILENSKY. Mr. Chairman and members of the committee, I am pleased to be here today to review the efforts that the Department of Health and Human Services has taken to improve the quality of laboratory testing.

Protecting Americans from life-threatening mistakes in laboratory testing is a high priority for the department. The public has every right to expect accuracy and quality in the results of critically important laboratory tests. Members of these committees have demonstrated their concerns about ensuring public safety in this area. I want to assure you that Secretary Sullivan and I am committed to publishing regulations to implement the Clinical Laboratory Improvement Amendments of 1988.

Since I became HCFA Administrator in mid-February, Dr. Sullivan and I have met on several occasions to work through issues and advance these important CLIA regulations toward publication. I am pleased to report that we have forwarded a final copy of the

clinical lab regulations to the Federal Register for publication on March 14th.

This regulation takes a significant step toward protecting our citizens from poor-quality laboratory services. The rule greatly strengthens quality requirements for some 12,000 laboratories under HCFA's regulatory control. It is the first in a series of regulations that HCFA will issue this year to fully implement the Clinical Laboratory Improvement Amendments of 1988 and includes all the proficiency testing and cytology requirements in CLIA.

The publication of our final regulation marks the first time uniform national standards have been developed for proficiency testing, including cytology proficiency testing, and for quality control in cytology testing. In short, this regulation represents a significant advance in assuring the quality of laboratory service. More importantly, it provides needed protection for our citizens. In particular, adherence to the new, tough standards for Pap tests will help ease the concern of millions of women who fear cervical cancer.

The final rule relies on three components to ensure the quality of laboratory testing: Proficiency testing performance standards; quality assurances and personnel standards at the testing site; and a program to monitor and enforce compliance with standards. All laboratories will be required to participate in the proficiency testing program. Proficiency testing provides a measure of how well laboratories actually perform their tests. On a periodic basis, usually quarterly, laboratories will be required to conduct tests on proficiency testing samples for each specialty and subspecialty test that they perform. The tests are provided by a federally-approved private, nonprofit or State-run proficiency testing program that will evaluate and grade each test for accuracy. For laboratories that fail proficiency testing, Medicare and Medicaid will terminate, revoke, or suspend the laboratory's certification and cease payments for tests in question.

To be federally-approved, a proficiency testing program must assure the quality of its test samples. It must demonstrate a scientifically-acceptable process for determining whether tests have been accurately performed, and it must have the resources necessary to administer the proficiency testing program and provide reports to State agencies and the department.

One of the most important areas where stronger requirements have been called for is in cytology testing. Women rely on accurate testing of Pap smears to identify the early and treatable stages of cervical cancer. I know that you have particular concerns about cytology testing, and I want to describe in detail our new requirements in this area.

The new rule will strengthen cytology standards in three major areas: Personnel standards, proficiency testing and internal quality control.

Cytotechnologists will have to meet certain education and work experience requirements.

Each individual involved in cytology must also participate in proficiency testing no less than twice annually. At least once each year, individuals must participate in unannounced proficiency testing conducted on-site by State agencies in each laboratory. Individ-

uals must also participate in one of four off-site proficiency testing events conducted by State agencies at regional testing sites.

When proficiency testing identifies an individual's unsatisfactory performance, laboratories are required to provide immediate remedial training and education. Failure to do so will result in termination of the laboratory's Medicare approval for cytology testing. In cases where proficiency testing identifies an adequate performance, the last 500 negative slides read by an individual failing the proficiency testing will be reexamined.

The third major aspect of cytology testing reform involves new standards for quality control. These standards require that Pap smears must be processed separately from other specimens and handled in a manner that prevents cross-contamination. Diagnostic interpretations must not be reported on unsatisfactory smears. A maximum of 120 slides is permitted to be read by an individual during a 24-hour period. Laboratories must maintain records of the number of cytology slides screened and the hours devoted to screening by each individual during each 24-hour period.

Pap smears that are interpreted as suspicious or positive must be reviewed by a physician supervisor.

Laboratories must examine a 10 percent random sample of all Pap smears found to be negative, and laboratories must retain abnormal slides for 10 years and unsatisfactory preparations for 5 years.

As we gain experience with these new requirements, we should have better information to further improve cytology standards.

Although the impending publication of the final rule takes a significant step forward, we have more to do. The passage of CLIA coincided with our efforts to protect patient safety by improving the quality of laboratory performance. By enacting CLIA, however, the Congress also greatly expanded the scope of our regulatory responsibility in this area. The task that you have given us is immense.

All laboratories that perform any testing come under the purview of this law. We estimate that we will expand our jurisdiction from the 12,000 labs currently regulated to between 300,000 and 600,000 laboratories. This includes laboratories in physician offices, employer health units, public health departments, as well as other small establishments such as blood banks, mobile laboratories, and public health laboratories.

In the development of CLIA regulations, the Senate clearly intended that the Secretary consult extensively with experts in the field. Such consultation is necessary and appropriate.

In conjunction with our colleagues in the Public Health Services, we consulted with numerous associations and technical experts. Our discussions with the laboratory community provided invaluable information and guidance, but it also identified the tasks involved and the issues that had to be resolved.

As our discussions evolved, however, it became clear that the task of developing these regulations was considerably more formidable than we—and I believe that the Congress—had envisioned. The law presents us with technical and scientific challenges. The legislation requires HCFA to develop a new approach to laboratory regulation based on the complexity of the tests performed. The leg-

islation also gives the Secretary authority to exempt certain low-risk tests from regulation.

During our work with the laboratory professionals, we had difficulty reaching a scientific consensus defining the levels of testing complexity and in identifying those tests that could be defined as simple and low-risk.

We have now weighed the conflicting views. We have developed a proposed rule for public comment to implement the approach to the regulating laboratories envisioned by Congress. Now we want to publish this regulation as quickly as possible.

The proposed regulation will define three levels of testing. The regulation proposes greater personnel, quality assurance, and proficiency testing requirements for tests of increasing complexity. Certain tests, however, can be waived from regulation. Tests in the waiver level pose no reasonable risk of harm to the patient if they are performed incorrectly, are unlikely to yield incorrect results and require simple methodologies. A dipstick urinalysis is an example of a test that we propose to include in the waivered category.

We believe that this part of the legislation would be relatively simple to define. The intent of the waiver is clear—keep simple, low-risk testing out of the regulatory framework.

Congress recognized that simple tests performed in physicians' offices, particularly in rural America, should not be subject to unnecessary regulatory control. We were surprised, therefore, at the considerable debate among the experts in the field about what tests could be safely waived. We have made our best judgment and will invite public comment on this issue.

Tests proposed to be included in Level I recognize some risk of incorrect result, but the risk is minimized because the testing methodologies are not complex. Some judgment and knowledge are required to perform and interpret this level of testing. Cholesterol screening would be an example of a Level I test.

All tests not included in the waiver level or Level I categories would be put in Level II. Tests in this category pose reasonable and sometimes substantial risk or harm if performed incorrectly. The testing methodologies are complex, and performance and interpretation of the test require extensive knowledge and training. Pap smears and HIV tests would fall into this level of complexity.

The issue of which tests to include and which level of complexity was difficult to resolve. There is little experience to guide us in these decisions. Because this is an area of great interest to laboratories and physicians, we hope to receive specific comments on our proposal.

Later this year, the department will issue three additional regulations proposing requirements to implement other provisions of CLIA. One will establish certificate fees that Congress intended to fund the administrative costs of CLIA. Another rule will propose requirements for approval of accrediting bodies and State licensure organizations.

Finally, we will publish a proposed rule laying out enforcement requirements including the range of sanctions available to us for those who are not complying with CLIA.

In conclusion, the department will continue to vigorously pursue the development of regulations to ensure high-quality laboratory

services that more fully protect all Americans. Although we are behind schedule for implementing new regulations, the extra effort we are taking to discuss the issues with the laboratory community will ultimately benefit all of our citizens.

Thank you. I would be pleased to answer any questions that you may have.

[The prepared statement of Dr. Wilensky follows:]

STATEMENT OF

GAIL R. WILENSKY, PH.D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairmen and Members of the Committees: I am pleased to be here today to review the efforts the Department of Health and Human Services has undertaken to improve the quality of laboratory testing.

INTRODUCTION

Protecting Americans from life-threatening mistakes in laboratory testing is vital. Members of these Committees have demonstrated their concern about ensuring public safety in this area, and I want to assure you that Secretary Sullivan and I place a high priority on full implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

I am pleased to report that we have forwarded a final regulation to the Federal Register for publication next week that takes a significant step towards protecting our citizens from poor quality laboratory services. The rule greatly strengthens quality requirements for some 12,000 laboratories under HCFA's regulatory control, and is the first in a series of regulations HCFA will issue to fully implement the Clinical Laboratory Improvement Amendments of 1988.

CLINICAL LABORATORY REFORM

In late 1987 we undertook a complete revision of the Federal standards for the 12,000 laboratories participating in Medicare and Medicaid or engaged in interstate commerce. The proposed rule published on August 5, 1988 outlined three key components to

ensure the quality of laboratory testing:

- o Proficiency testing performance standards;
- o Quality assurance and personnel standards at the testing site; and
- o A program to monitor and enforce compliance with standards.

I want to emphasize that the development of this regulation was a complex and difficult task. In conjunction with the Public Health Service, we consulted extensively with professional laboratory organizations and individuals. The proposed rules generated over 1,600 comments that were carefully evaluated. While time-consuming, this process represents time well invested. The final rule reflects a deliberate and careful process that incorporates the contributions of the experts in the field.

The publication next week of our final regulation represents the first time uniform, national standards have been developed for proficiency testing, including cytology proficiency testing, and for quality control in cytology testing. In addition, the regulation clarifies and strengthens overall laboratory quality control and quality assurance requirements.

Let me describe the major provisions of the regulation which address proficiency testing, quality control and assurance, and cytology testing.

Proficiency Testing

Proficiency testing (PT) provides a measure of how well a laboratory actually performs tests. On a periodic basis, usually quarterly, laboratories will be required to conduct tests on PT samples for each specialty and subspecialty test they perform. The tests are provided by a Federally approved private nonprofit or State-run PT program, which will evaluate and grade each test for accuracy. The final rule establishes a national grading system by which all laboratories will be evaluated.

Laboratories will fail proficiency testing if they perform unsatisfactorily in two consecutive or two out of three testing events. In such instances, Medicare and Medicaid will terminate, revoke, or suspend the laboratory's certification and cease payment for the tests in question.

To be Federally approved to conduct proficiency testing under this regulation, a PT program must assure the quality of its test samples, demonstrate a scientifically acceptable process for determining whether tests have been accurately performed, and have the resources necessary to administer the PT program and provide reports to State agencies and the Department.

Quality Control and Assurance

Internal quality control requirements are strengthened and laboratory quality control programs are required to be updated to

account for new technology. A new quality assurance standard requires laboratories to establish an ongoing system to monitor the quality of its testing and to assure the performance and competency of its staff.

Cytology Testing

One of the most important areas where stronger requirements have been called for is in cytology testing. Women rely on accurate testing of Pap smears to identify the early and treatable stages of cervical cancer. Unfortunately, studies have shown that the quality of Pap testing is uneven. In some laboratories, the quality has been dangerously low. That situation cannot be allowed to continue. I know that you have particular concerns about cytology testing, and I want to describe in detail our new requirements in this area.

The new rule will strengthen cytology standards in three major areas: personnel standards, proficiency testing, and internal quality control.

Personnel - Cytotechnologists will have to meet certain education and work experience requirements.

Uniform Proficiency Testing - Each individual involved in cytology testing must also participate in PT no less than twice annually. At least once each year, individuals must participate

in unannounced PT conducted on-site by State agencies in each laboratory. Individuals must also participate in one of four off-site PT events conducted by State agencies at regional testing sites.

Laboratories are required to provide immediate remedial training and education when PT identifies an individual's unsatisfactory performance. Failure to do so will result in termination of the laboratory's Medicare approval for gynecologic cytology testing. In cases where PT demonstrates inadequate performance, the last 500 negative slides read by an individual failing PT must be reexamined. The individual will not be permitted to read cytology slides until a satisfactory PT grade is achieved.

We recognize the special problems involved in conducting a PT program for cytology. Because little cytology PT has been routinely conducted in the past, PT samples are not widely available. PT programs will need some time to assemble patient samples and to prepare slides for testing. In addition, arrangements to conduct the cytology PT will require coordination between the PT program, the State inspection agency, and the laboratory. With little experience to guide us in developing a cytology PT program, we have attempted to strike the appropriate balance between structuring an administrable process and adequately assuring quality.

Internal Quality Control - Our quality control standards for cytology require that:

- Pap smears must be processed separately from other specimens and handled in a manner which prevents cross-contamination;
- Diagnostic interpretations must not be reported on unsatisfactory Pap smears.
- A maximum of 120 slides is permitted to be read by an individual during any 24-hour period. No individual is permitted to read the maximum number in less than 6 hours. Recognizing that not all individuals may be able to accurately examine 120 slides a day, physician supervisors are required to evaluate each individual's screening capability and to determine individual maximum workloads.
- Laboratories must maintain records of the number of cytology slides screened and hours devoted to screening by each individual during each 24-hour period.
- Pap smears interpreted as "suspicious" or positive must be reviewed by the physician supervisor and the record documented to reflect this review.
- Laboratories must reexamine a 10 percent random sample of all Pap smears found to be negative.
- Laboratories must maintain abnormal slides for 10 years and unsatisfactory preparations for 5 years.

These requirements for cytology testing include all of the CLIA provisions for cytology, and represent a significant advance in assuring the quality of these critical laboratory services. Our

experience with these new requirements should provide us with information to further improve our cytology standards.

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

The passage of CLIA coincided with our efforts to protect patient safety by improving the quality of laboratory performance. By enacting CLIA, however, the Congress also greatly expanded the scope of our regulatory responsibility in this area. The task you have given us is immense.

Expanded Regulatory Responsibility - All laboratories that perform any testing come under the purview of this law. We estimate that we will expand our jurisdiction from the 12,000 labs we currently regulate to between 300,000-600,000 laboratories. This includes, for example, those laboratories in physicians' offices, employer health units, public health departments, as well as other small establishments such as blood banks, mobile laboratories, and public screening laboratories.

Extensive Consultation: The Senate clearly intended that the Secretary consult extensively in the development of CLIA regulations. Such consultation is necessary and appropriate. To quote the Senate Committee Report, "The Secretary would be required to consult with appropriate private organizations and government agencies in the development and implementation of appropriate standards and criteria." (Senate Report 100-561 dated

September 29, 1988).

In conjunction with our colleagues in the Public Health Service, we consulted with numerous associations and technical experts. Our discussions with the laboratory community not only provided invaluable information and guidance, but also identified the tasks involved and the issues that had to be resolved. As our discussions evolved, however, it became clear that the task of developing these regulations was considerably more formidable than we, and I believe the Congress, had envisioned.

Technical Challenges - The law presents us with technical and scientific challenges. The legislation requires HCFA to develop a new approach to laboratory regulation based on the complexity of tests performed. It is the nature of the test, rather than the site of that testing that will determine the level of regulatory control. The legislation also gives the Secretary authority to exempt certain low-risk tests from regulation.

During our work with laboratorians and professional groups, we had difficulty reaching a scientific consensus on defining the levels of testing complexity and identifying those tests that could be defined as simple or low risk. We have now weighed the conflicting views. We have developed a proposed regulation for public comment to implement the complexity model envisioned by Congress. Now we want to publish this regulation as quickly as

possible.

The proposed regulation will define three levels of testing based on the complexity of the tests performed. The regulation proposes greater personnel, quality assurance, and PT requirements for tests of increasing complexity.

The Waiver Level would include tests that can be waived from regulation because they pose no reasonable risk of harm to the patient if performed incorrectly, are unlikely to yield incorrect results, and require simple methodologies. A dipstick urinalysis is an example of a test we propose to include in the waiver category.

We believed that this part of the legislation would be relatively simple to define. The intent of the waiver is clear -- to keep simple, low risk, testing out of the regulatory framework. Congress recognized that simple tests performed in physicians' offices, particularly in rural America, should not be subject to unnecessary regulatory control. We were surprised, therefore, about the considerable debate among the experts in the field about what tests could be safely and rather simply waived. We have made our best judgment and will invite public comment on this issue. I would emphasize that we do not view the waivered tests as "fool-proof." The tests require proper adherence to quality testing practices, but they do not require the amount of

detailed, quality oversight as other tests.

The remaining tests would be categorized according to the degree of risk involved if they are performed incorrectly and the complexity of performing the test. Level I would permit some risk of incorrect result, but it is minimized because the testing methodologies are not complex. Some judgment and knowledge are required to perform and interpret this level of testing. Cholesterol screening would be an example of a test in this complexity level.

Level II of complexity would include all tests not in the Waiver Level or Level I categories. Tests in this category pose reasonable and sometimes substantial risk of harm if performed incorrectly. The testing methodologies are complex and performance and interpretation of the test require extensive knowledge and training. Pap smears and HIV tests would fall into this level of complexity.

The issue of which tests to include in which level of complexity was difficult to resolve. There is little experience to guide us in these decisions. Because this is an area of great interest to laboratories and physicians, we hope to receive specific comment on our proposal.

Other CLIA Regulations

Later this year, the Department will be issuing three additional regulations proposing requirements to implement CLIA. One will establish certificate fees that Congress intended to fund the administrative costs of CLIA. Another rule will propose requirements for approval of accrediting bodies and State licensure organizations. Finally, we will also publish a proposed rule addressing the enforcement of CLIA requirements including provisions for intermediate sanctions; suspension, limitation, or revocation of a certificate; hearing and appeals procedures; and civil and criminal penalties, including the assessment of fines.

The CLIA regulations we will shortly propose represent our best efforts to implement new approaches to assuring quality laboratory services. Consequently, I want to stress that we have reached no final conclusions and need full public comment on these important regulations.

CONCLUSION

In conclusion, the Department will continue to vigorously pursue the development of regulations to ensure quality laboratory services that more fully protect Americans. Although we are behind schedule for implementing new regulations, the extra effort we are taking to discuss important issues with the laboratory community will ultimately benefit all our citizens.

Thank you. I would be pleased to answer any questions you may have.

Senator ADAMS. Thank you very much, Dr. Wilensky.

Senator Levin.

Senator LEVIN. Welcome, Dr. Wilensky.

As I understand it, you are about to issue regulations which will apply to about 12,000 labs.

Dr. WILENSKY. Correct.

Senator LEVIN. The CLIA regulations would apply to somewhere between 300,000 and 600,000 labs or facilities, as you indicate.

Dr. WILENSKY. Right.

Senator LEVIN. The CLIA regulations include the 12,000 labs that are covered by the August 5 regulations which you brought with you today.

My first question is why did you spend your resources on those August 5th regs, as they are sometimes called, instead of focusing on the statutory deadline for CLIA, when we are supposed to have the final CLIA regs in place by January 1 of 1990?

Dr. WILENSKY. We believe that because a proposed rule had already existed before the passage of CLIA 1988 and that comments had begun to come in about that proposed rule that it would be better for us to go after that one area that was already in process that looked at the tests that were being performed by laboratories that were doing Medicare and Medicaid work and to try to proceed as expeditiously as we could in that area as well as beginning to work on CLIA thereafter. But it was because work had been in progress, had started, and we felt that we would be able to improve safety in that area by taking advantage of the work that had already been done.

Senator LEVIN. Were some people pulled away from the CLIA regs in order to work on the August 5 regs?

Dr. WILENSKY. These regs were already in process before CLIA.

Senator LEVIN. But to complete those regs in the shape that they are in now—are those not the same people who would be working on the CLIA regs?

Dr. WILENSKY. It is not our opinion that the number of people who were available to work on the regs, of which our estimate has been at least 50 have been involved in that process, was a delaying factor. The delaying factor had been the complexity and lack of consensus in the scientific community on which to judge complexity issues for testing.

Senator LEVIN. Well, at some point, you found out that the regulatory task, as you phrase it in your testimony, was fundamentally more difficult than you had expected. When did that become clear to you?

Dr. WILENSKY. It became clear as we pursued, per the intent of the legislation, discussions in the scientific community about how to implement——

Senator LEVIN. About what time did it become clear? When, chronologically, did that become clear?

Dr. WILENSKY. My sense is it became clear during the period in 1989 when various conferences were being held and meetings were going on in the scientific community to try to understand whether or not there was agreement on what would be regarded as low-risk or no-risk tests, so that a distinction could be made between waiver and Level I.

Senator LEVIN. What is your schedule now for issuing the CLIA regs?

Dr. WILENSKY. We are very close, we believe within a month of issuing the proposed rule for implementing the CLIA regs. There are three others that are involved. The next one and this last one is now under review in the Office of the Secretary.

The next one that we expect to be available as a proposed rule will be the one concerning laboratory fees——

Senator LEVIN. No, not those, not those additional three; just the principal regs. How would you describe the regs which you indicate will be published in a month?

Dr. WILENSKY. That will be the ones that describe the different levels of complexity and which tests are in what categories.

Senator LEVIN. And you expect that you will propose those and publish those by the middle of April.

Dr. WILENSKY. That is our hope.

Senator LEVIN. And are the August 5 regs which you are going to publish this month going to be incorporated into the CLIA regs, or will they be superseded by the CLIA regs?

Dr. WILENSKY. This final rule that will be published next week contains the cytology testing proficiency standards that I just spoke about. And everything in here is consistent and includes the CLIA with regard to the CLIA 1988 with regard to cytology. The main differences have to do with the movement away from regulations according to the site of the laboratory testing and to focus strictly on the complexity.

Senator LEVIN. Will there be differences between that rule and the regs that you are going to propose in the middle of April?

Dr. WILENSKY. Not in any fundamental way that I am aware of, other than in personnel standards. There is some difference with regard to that because of the fact that the regulations relate to the complexity of the test and no longer to the site of test.

Senator LEVIN. So that you will, in effect, be repealing part of the August 5 rule with the regs which you will be proposing later this year on CLIA; is that correct?

Dr. WILENSKY. The tests that are in here are in the Level II testing only, the cytology testing——

Senator LEVIN. Will there be any conflict between the regs which you are going to propose later this year, implementing CLIA, and what you are publishing in the August 5 rule?

Dr. WILENSKY. I believe only with regard to some personnel requirements, nothing else.

Senator LEVIN. The answer is "Yes, some"?

Dr. WILENSKY. There are some. The answer is almost none. It was my understand that there was some area of overlap, but I don't have a good sense of how much that is. My experts say——

Senator LEVIN. That seems awfully wasteful to me to be proposing regs this month, or right now, which are going to be superseded next month.

Dr. WILENSKY. I think that the primary concern we had and the focus of this regulation has to do with setting up uniform national standards, setting up proficiency testing, setting up quality control in the laboratory, and none of that is going to be superseded. All of that will remain, and we think that was an important contribution.

Senator LEVIN. My time is up. Thank you.

Senator ADAMS. Senator Cohen.

Senator COHEN. Thank you very much, Mr. Chairman.

I'd like to turn to the issue of enforcement. HCFA has had enforcement powers long before CLIA 1988. In fact, in 1987 as part of the Omnibus Reconciliation Act, HCFA was given additional authorities for enforcement, and in fact nothing occurred as a result of those particular expansions of power.

Labs in the Medicare program have been under, HCFA's jurisdiction for years. In your judgment, why the lack of enforcement? We've had expanded powers given to HCFA for intermediate sanctions. They were due in January, as I recall, of 1989, and nothing has been done about intermediate sanctions.

Dr. WILENSKY. With regard to the past, I will give you my sense as best I understand it. There have been terminations, as you know, of laboratories that are conducting tests, but they have not been large numbers of terminations, but there have been.

I believe that one of the issues that we have lacked is this information on uniform national standards that we will hold labs to with very specific information as to what it is we will expect them to do, how it is we will go about testing that, and a very timely basis for having that testing occur.

Senator COHEN. Well, the point I'm getting at is that you are talking now about regulations for cytology, but the cytotechnologists have been complaining since as early as 1981 about the absence of standards and proficiency testing and other things, and yet nothing has been done. So has it been an attitude that this has not been a high priority? You indicated in your opening remarks that this is a very high priority. But the work record doesn't seem to reflect that in terms of the length of time in which the concerns have been raised and the actual production of the regulations.

Dr. WILENSKY. I think somewhat to the surprise of HCFA was the response that was received after the proposed rule was published in August of 1988. Over 1,600 responses were received. There was a tremendous amount of discussion and disagreement in the scientific community. There is still some disagreement in the scientific community, and as you may be aware, while this is a final rule, it is being proposed as a final rule with a 60-day comment period to again allow groups and individuals to make comment.

I think that the degree of dissension and disagreement in the scientific and technical community really did come as a surprise to the people at HCFA and to the colleagues in the Public Health Service that we rely on extensively, the CDC and the FDA, to give us guidance on this issue.

Senator COHEN. Let me ask you about that question. There have been a number of draft reports that have been leaked to the press over a number of months. The most recent draft report was released, I think, on Valentine's Day, February 14. But aside from the Valentine card that was sent, it seems to me that it reflected a revision over what was leaked earlier.

The question I have, for example, is the revisions on the February 14 draft recommendations seemed to include recommendations coming from Centers for Disease Control and FDA. Were they included in the initial consultation process?

Dr. WILENSKY. Oh, yes, oh, yes. This has all been involving them from the beginning as HCFA usually does on issues as technical as this.

Senator COHEN. So they were consulted from the very beginning, and any change in the waiver category or Category I was not due to any change in opinion reflected by CDC or FDA?

Dr. WILENSKY. It was continuing and evolving discussion, as again this has been a process that went on for a long time, continuing interactions. I was there during this part, and it was with the agreement of our experts in CDC and FDA that we have come up with this final proposed rule.

Senator COHEN. Do you have a scientific rationale for the determination of why each individual test ought to be placed in either Category I or waiver?

Dr. WILENSKY. My sense is—and I haven't asked that question to the experts specifically—my sense is that they were able to come to some consensus about what tests reasonably could be regarded as low-risk, although initially when the issue was raised as are there some tests that have no risk whatsoever, that that caused a lot of concern, and that over time, through discussions in the scientific community, the opinion became shared that those that had very little reasonable likelihood of causing harm or being done incorrectly could in fact be regarded as a waiver. But my impression is that it is the consensus of opinion of experts and that there is not a strict litmus test of a scientific nature that is distinguishing them.

That's my personal opinion.

Senator COHEN. So the answer is there is no scientific basis for the establishment of the criteria other than trying to develop a consensus among the competing expert opinion.

Dr. WILENSKY. Experts in the area, based on criteria that they lay out.

Senator COHEN. Well, there is some concern about this. I had a letter, for example, from the American Society for Medical Technology, and they have expressed concern over several of the waivered tests on the grounds that they are used to detect serious conditions which—and I'm quoting here—"if missed, can lead to more serious disease". And they give an example of a gram stain which, "if done incorrectly, could result in the wrong class of antibiotics being prescribed, allowing an infection to escalate; the anti-strep test is crucial to preventing complications of strep throat. If this isn't performed properly, a false-negative result could lead to rheumatic heart disease and potential permanent damage to the patient's heart or kidney and thus a false-negative can doom a patient to life on renal dialysis."

So the question becomes whether you think that tests with these types of consequences should be performed without proficiency testing?

Dr. WILENSKY. I'm an economist. I don't know whether that is a reasonable test to put in a waivered category. I think——

Senator COHEN. If you don't know, how do we know, then?

Dr. WILENSKY. Because I rely on the expert advice of the people in FDA and CDC to give me their best opinion. With regard to the example, however, that you raised, I'd like to remind you that the proposed rule has not been published yet; when it is, it is precisely

for the purpose that experts in an area if they disagree—although I am sure they were consulted, or people like them at some point—will have a normal comment period to say "We disagree. This is not a good test to put in the waiver." That is the purpose for that comment period.

Senator COHEN. Well, the question I have is whether or not these types of tests should be performed without proficiency testing, without quality control, and no requirements for qualified personnel, which would be the case for the waivered category.

I guess I have a question as to how can you read any test with a microscope, which requires interpretation, and fit that into a waivered category. I don't understand that.

Dr. WILENSKY. Again, my understanding of the decisions that were used to make this trade-off were to try to not have every, single laboratory, physician office, included into a regulatory setting if it was believed that there were some kinds of tests simple enough that were only performed in settings that did not pose risk to the patient, and that could be done by somebody with very little training and where there was very little likelihood of incorrect results.

There may well be disagreements about the tests we've put in. We'll have that come out in the comment period, and we will revise it if there is a sense of the community that that was not appropriate and that that is agreed to by our own technical advisors.

Senator COHEN. Mr. Chairman, could I just add one point?

Senator ADAMS. Certainly.

Senator COHEN. The latest draft of the CLIA 1988 regs that I have seen wouldn't require any personnel standards for individuals performing Level I tests. I believe that's the case. In view of the fact that the majority of physicians themselves have no expertise in lab training, how are they going to be in a position to assure the competency of the people in Category I?

Dr. WILENSKY. These are cases where the physician will be responsible for what goes on in the lab.

Senator COHEN. But he has no training in that category. In other words, the majority of physicians do not have training in reading these types of tests. So you are going to have him in charge of someone where there are no personnel standards established.

Dr. WILENSKY. But he is in charge of what is going on in that office, both in charge and liable for what happens there.

Senator ADAMS. Doctor, nobody is watching the store that knows the answer.

Dr. WILENSKY. I beg your pardon?

Senator ADAMS. Senator Mikulski.

Senator MIKULSKI. Thank you, Senator Adams.

Dr. Wilensky, I have a couple of questions, and you will sense in my voice a real level of frustration and even irritation. I want to be clear that it is not directed at you. I want to give you a very cordial welcome to this joint committee hearing. I think the Administration is very fortunate to be able to recruit someone of your experience and expertise to really take over the Health Care Financing Administration, which has not had a permanent leader in some time.

We know your field is economics, and in many ways that is the primary mission of HCFA. We look forward to working with you as we go through this hearing, that has its own tensions to it, and you should know how we really feel about you personally and what you bring to this post.

I'm going to ask a straightforward question as if the consumers were here, as if ordinary people were here. Their questions will be: When am I going to be better off? When I am going to be safer? Not when CLIA Part 5 is implemented or the August 5th reg or OMB signs off, or all of those kinds of things—but when will we truly see the impact at the laboratory level, where consumers can feel safer, more protected, that their tests will be more reliable. When will this be fully operational at Main Street?

Dr. WILENSKY. Well, I think that I have to say it is in two pieces, at least, and I will try not to do the five-part.

I believe that the final rule that will be published next week will make a tremendous difference in the areas in which it operates, which are the Medicare and Medicaid plans. I truly believe that the kinds of proficiency testing that is there and the internal quality controls and the monitoring that is provided in this reg will make a major difference for all of the labs that have traditionally been under HCFA's control, Medicare, Medicaid and interstate commerce labs.

So I think that part of my answer would be for anything that goes on within that context, I believe that this rule will make a difference.

With regard to the other, I appreciate——

Senator MIKULSKI. Well, Doctor, when will it be felt, though, at the laboratory level, in Maine or Maryland or Washington or Michigan?

Dr. WILENSKY. Sixty days. Sixty days is when it is operational.

Senator MIKULSKI. At the laboratory level or at the State level?

Dr. WILENSKY. [Conferring with staff.] Excuse me. That was not quite correct. It is staged in. Part of it will come in in 6 months and part of a it in a year in terms of the proficiency testing.

Now, with regard to the other large numbers of laboratories that are are not Medicare and Medicaid laboratories, I don't know what will happen—I feel quite confident that the proposed rule will come out shortly in the next month. What I don't know is whether there will be a massive amount of comment—I guess I won't be surprised, but I don't know—and how long that will take to resolve.

I will tell you that I am very concerned about the length of time that has passed. I was not here—I only have a sense of what I was told as to why that occurred. And I will do everything I can to expedite that process.

If there are thousands of responses that HCFA needs to deal with in accordance with the comment period, it will take some time to deal with that, and it is hard for me to give you a time on that.

Senator MIKULSKI. Well, Doctor, that is one of the reasons for the frustration. Our question is what was the groundwork being done even to do the clinical labs. Has the Health Care Financing Agency begun the process of finding out what kind of testing is done at

what sites; the inventory of that? As we indicated earlier, 5 years ago we were beginning to raise these questions. What is your database? How do you know what you are getting into? And even if you get a lot of comments, are we talking about 3 months, 6 months, 2 years?

Dr. WILENSKY. Well, I think what it really depends on is whether we are talking—normally, when HCFA puts out a proposed rule, the number of comments that it receives back is in the nature of a few hundred. With regard to the rule that is now being published in final, we have received over 1,600 comments.

Now, before we have done the CLIA 1988 proposed rule that will be coming out shortly, there has been a tremendous amount of interaction in the scientific, technical and professional communities. We have done our best to try to hear what these groups are saying, but the fact of the matter is in the end, you take this information, you have your own technical and scientific experts try to come to the best consensus they can about how to proceed.

But there was a lot more dissention as to whether or not there were tests that could properly be regarded as low-risk and waivered and that the whole complexity model that was embodied in the legislation assumed scientific information that our technical people have indicated just doesn't exist.

Are we going to get thousands of responses? I don't know. We will try to deal with it just as quickly as we can. But I don't know—if three our four thousand responses come in, I guess I don't know well enough how long it takes to deal with that kind of a volume.

Senator MIKULSKI. Well, can you estimate it? How long will it take to go through 1,000 responses?

Dr. WILENSKY. [Conferring with staff.] The answer I have is that it depends on how technical they are.

Senator MIKULSKI. Well, you see——

Dr. WILENSKY. I understand what you're trying to ask. I just don't know how to——

Senator MIKULSKI.You understand. That's exactly what we get all the time. And the yellow light is on, and we will have a second round. But let me just say this. You have there the August 5th regulation. You hold it up with pride, and you should, because you moved that. Our frustration is that the legislation we passed was the Clinical Lab oratory amendments of 1988, which we think incorporated our frustrations there.

Dr. Wilensky, can I have your commitment as the new head of HCFA that when Congress passes a law and it is signed by the President of the United States, that it will be implemented regardless of what regs are pending, or there will at least be consultation with the Congress to see if there is something you or we are doing that would impede the progress of protecting American citizens? Will you implement the law when we pass it?

Dr. WILENSKY. I will either implement the law or indicate to you why we are having difficulty and cannot.

Senator MIKULSKI. That would be a refreshing situation.

Dr. WILENSKY. One of the issues that I have undertaken in coming into HCFA is to set up a task force to do a review of how the regulations process is formulated and reviewed in HCFA, re-

viewed within the department, and then interaction with other agencies. It is supposed to come back to me in the next 45 days. I am troubled with this process, and I would like to make it better.

Senator MIKULSKI. We look forward to those comments, and we also know you are taking the bold step of setting up a separate Medicaid division, and we look forward to working with you on that.

Thank you, Mr. Chairman.

Senator ADAMS. Dr. Wilensky, I want to echo the comments of my colleague Senator Mikulski that we look forward to working with you. You write on a clean slate here. It will rapidly become dirty or stay clean depending upon the results that we get because, as you can see, we have a number of people here who have worked on this a long time.

I have some familiarity with issuing regulations out of departments.

I am very concerned—and you are an economist—about the database that you have. As I listen to your testimony and as I have read it and tried to follow it, it does appear to me you can get these August 5th regulations on the street—and I think how long it has taken to do so is horrifying—to cover proficiency testing, which is one of our primary problems. Laboratories are not working well and are not being inspected, people are being overworked, working in one lab and doing 200 to 300 eyeball tests and then going out and moonlighting that night and doing the same thing all over again. What bothers many of us is that these are human tests.

Now, my question to you is that you are dealing there, really, with 12,000 laboratories that are Medicare or Medicaid. You indicate in your testimony that there may be as many as 300,000 to 600,000 laboratories.

I need to know in that gap between 12,000 and 300,000 or 600,000, is your department—or have you hired somebody else to determine what is the status of that enormous number of laboratories that will not be covered, checked, or tested under your August 5th regulations.

Dr. WILENSKY. Each laboratory will be identified through the inspection and certification process that will be part of the implementation of the CLIA. That is, in order to——

Senator ADAMS. When will that happen?

Dr. WILENSKY. It won't happen until the rules are implemented.

Senator ADAMS. And those rules haven't been started yet.

Dr. WILENSKY. The first of them will be proposed, we believe, in a month.

Senator ADAMS. So those will get on the street in about 2 years.

Dr. WILENSKY. I would hope we can do better than that.

Senator ADAMS. All right. Now, one thing that I advocated in the original bill, and it wasn't accepted in it, which would help cure this problem was a direct billing system of the laboratory fees. There were two reasons for that. One was to see whether physicians and others were simply ripping people off—in other words, raising their fees. The second was it gave you information as to where these things were going. Do you visualize starting some kind of system like that to locate these other laboratories?

Dr. WILENSKY. My understanding is that the way they will be located is through the inspection and certification process that every laboratory will have to go through in order to have it deemed as waivered Level I or Level II; that these inspections will occur on a biannual basis, and it is at that point that we will in fact have established how many of the laboratories exist, not only the ones we usually think of in the physician office visit or independent clinical labs, but these mobile units and other types of small labs.

Senator ADAMS. All right. Now, that goes to the ones that we heard about. We are worried about the Pap mills and the formation of large numbers of physicians' laboratories where they can make a certain amount of money on that and are conducting large numbers of tests. Now, I want to ask you this very carefully. If I form a laboratory with a group of physicians and a group of entrepreneurs—take any State; California happened to have a lot of them, but pick a State with rules not quite as strict as some of the others. We do not take Medicaid patients and we may not be taking Medicare people—we do not have Medicaid and Medicare. How do you find them—they aren't under those regulations, are they?

Dr. WILENSKY. They are not under these regulations; you are correct. They are under the CLIA 1988 regulations. Again, each of these are now under the purview of the Health Care Financing Administration, or will be when the rules are promulgated.

Senator ADAMS. Now, have you got a process for finding them? I am not asking this in a vacuum. But testimony came out and we heard from both patients and from others that some doctors were trying to get the lowest possible fee. That is why these Pap mills grew up, and I just refer to that, but they do other testing, too. But they would try to get this lowest fee, and it was all done by mail so that you could have some very large laboratories, who were the worst offenders—in other words, they were trying to cut fees, working people 300 slides a day and then 300 at night, or letting them take them home—that wouldn't be under Medicaid or Medicare.

I just want to know whether or not that group exists, because if they do, I want to know when they are reached and how you are going to reach them. And I cannot tell from your testimony because it says there are 100,000 to 300,000.

Dr. WILENSKY. I understand.

Senator ADAMS. OK. And I am worried about Senator Cohen's problem where you've got a doctor and a lab technician, and neither of them know what they are doing—that's a separate problem that bothers me. But right now I want to focus on the big problem where we were killing a lot of people.

Dr. WILENSKY. OK. The direct answer is all labs as a result of the CLIA 1988 Amendments will have to be licensed, and the State health department will be inventorying all labs. So the answer——

Senator ADAMS. Now, you have that in regulation. How is that being done?

Dr. WILENSKY. Well, that will be part of the regulations.

Senator ADAMS. Are you writing each State and saying, "Tell us the labs"? I am just asking the kinds of questions that Senator Mikulski did. I've got my wife in a lab, and I don't think she should have to go through checking the sparkplugs and say I want to see

direct billing, and ask, "Are you sending my smear to laboratory X or Y; are you doing it down in the basement, or where are you doing it?" That's not her specialty. She relies on it.

Dr. WILENSKY. It is one of the new proposed rules as part of CLIA 1988 that will be issued as how we will go about dealing with enforcement. There are four rules that will———

Senator ADAMS. Well, what have you said to the States or to whomever you have said it to as to how you are going to locate or determine your database of 300,000 to 600,000 labs—if there are that many?

Dr. WILENSKY. Well, I don't think we know. I think one of the issues is that we do not know exactly what the number is, and that's why the range is in there. Again, as a result of this legislation, when it is implemented, which it cannot be until these proposed rules are written and final rules are formed, all labs will now be licensed so that———

Senator ADAMS. Can't you put out interim rules that require that?

Dr. WILENSKY. I don't believe so.

Senator ADAMS. I'll tell you what. Call over to the Department of Transportation and ask them how you put out interim rules on bridges that you think are in danger, and they will tell you how to write a set of interim rules that will allow you to get an original registration. Would you try that?

Thank you.

Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

Dr. Wilensky, in Michigan we have about 325 labs which will be regulated by the August 5th rule that you are going to be publishing. We estimate we have 10,000 to 20,000 labs awaiting the CLIA regs. I believe that HCFA, not you, but HCFA, misdirected its resources by pursuing these regs, these August 5th regs, and causing a delay in the CLIA regs. That's my own personal opinion. The CLIA regs are required by law. This rule, as I understand it, was not required by law. You had the choice as to whether to go full-speed ahead to cover the larger number or to continue to pursue something you had already begun, which covered the smaller number. It is my belief it would have been better to go directly to those CLIA regs. Now we are going to see a further delay in those regs.

The problem that creates, for instance, for a Michigan resident, is that they are not going to know before those CLIA regs come out whether or not the lab they use is going to be covered or not covered by Federal regulation. We are going to have a published rule within a month or so which will cover relatively few labs. These covered labs may do a greater proportion of the tests, but it is still relatively few labs. We've still got those 300,000 to 600,000 labs that are not covered and that will be in limbo until we have the CLIA regs published.

That's a real dilemma. Do you know about what percentage—take Pap smears—are done in labs which will be covered by this August 5th rule, and what percentage would be covered by the CLIA regs? Can you just give us a ball park figure on that?

Dr. WILENSKY. Seventy-five percent is the estimate, I have been told.

Senator LEVIN. Will be covered by this rule. So about three out of four Pap smears will be covered by the August 5th regs. Even though there are many more labs or offices or facilities that are involved in the 300,000 to 600,000, they represent ball park about 25 percent of the Pap smears testing?

Dr. WILENSKY. Yes.

Senator LEVIN. OK.

Dr. WILENSKY. Most of the Pap smears are not done in physician offices. That is why they are in that Level II category.

Senator LEVIN. Now, will that be typical of other tests? Do you think that figure is a typical one?

Dr. WILENSKY. It is not going to be typical of the very simple tests that we have now waivered. In fact, there are a number of very simple tests that are done in physician offices, typically, that are not likely to be in there.

Senator Levin, may I just comment with regard to the delay issue?

Senator LEVIN. Sure, of course.

Dr. WILENSKY. I don't know why it took so long to get the CLIA 1988, and I think that you are entitled to be frustrated; I am frustrated as well, and I will do everything that I can to have this next round move more expeditiously.

I do not think, however, the delay was because of the rule, and again I would just beg to differ with you. I believe the delay was a reflection of the major unexpected dissension in the scientific community about this complexity testing, and I do believe this will make an important contribution. I truly do not believe it was the cause of the delay.

Senator LEVIN. One thing you could do to give us some more reassurance about the CLIA regs would be to give us a range as to when we can expect that rule. Senator Mikulski attempted to get an estimate from you, and you indicated that when those rules would be published would depend in part on how many responses and how complex those responses are, and I think we can understand that.

Still, can you not give us some kind of an estimate as to when we can expect a proposed reg to be published?

Dr. WILENSKY. I think the time that I can give you, an expected time limit, and maybe this will provide a little reassurance, is as soon as the comment period is over and we have any idea what we are up against. If we are indeed able to have this in the Federal Register within a month's time—there will be a 90-day comment period. At that time I think that I could give you a reasonable assessment. I have inquired repeatedly as to whether, before that, I can give you a reasonable assessment, and I have not been able to get that information.

Senator LEVIN. You haven't been told whether you could estimate that it will be 6 months after the comment period or a year after the comment period, for instance?

Dr. WILENSKY. What I have been told is that without a sense about how much real technical disagreement is going to result as a result of this publication, since there was a lot of miscommunica-

tion about what is really coming out—there have been various leaked drafts, and people get all upset and have been writing in about leaked drafts that it turns out are not relevant—it is difficult for me to have an assessment about whether, even if they are a large volume, whether the kinds of comments that are going to come in are going to reflect serious technical disagreement that would cause CDC and FDA scientists to respond in a very different way than if they are a different level of comment.

Senator LEVIN. You can't even tell us that by this time next year, you are going to have a published reg.

Dr. WILENSKY. The answer is that we will do everything we can. But I think I can give you a much better sense as soon as that comment period is——

Senator LEVIN. Will you let our committees know at the end of the comment period what your timetable is?

Dr. WILENSKY. Absolutely, absolutely.

Senator LEVIN. My last point is that numerically, using the number of Pap smears that are done in a year, that 25 percent figure, if that is a correct ball park figure, would still leave about 15 to 20 million Pap smears a year that would be done in labs which are not covered by the August 5th regulation, because the total estimate is that somewhere between 50 and 90 million Pap smears are done in a year. That is still a huge number that are awaiting some kind of assurance that we've got some regulation. So we will await that timetable at the end of that 90-day period.

Dr. WILENSKY. I understand.

Senator LEVIN. Thank you.

Senator ADAMS. Senator Cohen.

Senator COHEN. Dr. Wilensky, if you detected some skepticism up here, I want to tell you why. I was just looking at a copy of the transcript of the hearing we had back in 1988, and I was asking a question of Mr. Lewis Hayes who was, I believe, the assistant administrator at that time. I asked him a question as to why they had waited so long to implement the recommendations made by the American Society of Cytologists. They were under contract with HCFA back in 1981. They indicated that some of the labs were doing 300 slides a day; one individual might be required to do 300 slides a day, without supervision, without personnel standards, without proficiency testing. And I raised the question as to why has it been so long and no action taken. And at that point, Mr. Hayes said, "Well, the fact of the matter, sir, is that we are addressing that problem both through our current activities and through the proposed regulations that we hope will be on the street by the end of next month."

So it has a familiar ring to it, that here we are 2 years later, and "by the end of next month" is also being suggested to the committee. So I think that is part of the reason for the frustration. It seems to be it is always "by next month" that we keep waiting for.

Second, I have a question in terms of the test classification. You indicated that you haven't really established the basis for the classification yet. In your opening statement, you indicated how you are going to decide between those in the waivered category, Category I and Category II. That is essentially the same language that the statute set forth. I mean, there is nothing new in terms of the regu-

lation language. But you haven't made a determination yet as to whether there is a scientific basis for the classification itself. And I guess we are left with the conclusion that there is no scientific basis. All your experts can hope to do—and I assume that means FDA and CDC—is try and look through all of the conflicting recommendations and come up with some kind of a consensus. I am not sure that that is going to be adequate in terms of setting the standard, and frankly, I think it should have been done. It was due in January of this year, and we are looking a long way away from that point in terms of establishing the basis for the classification system itself.

Could you tell us—and you don't have to do it now, but for the record, at least—which groups you have been consulting with both within and outside the department in developing the list of tests that you will have for the categorization of those in the waivered category and so on?

Dr. WILENSKY. Senator, I have it if you would like to know, but I could give it to you for the record.

Senator COHEN. Yes, if you could just submit it for the record so we'll know exactly whom you have been dealing with.

[The information referred to follows:]

CONSULTATION IN REGULATIONS DEVELOPMENT

Conferences Attended

National Laboratory Conference—11/15-16/88
Conference with FDA on status and coordination of CLIA implementation—2/15/89
Technical conference with CDC on waiver tests—3/27-28/89
Critical Issues Conference with CDC—4/10-12/89
Conference with the American Society for Cytotechnology—4/14/89
Conference with the National Council Health Laboratory Services—4/15/89
American Pathology Federation's national meeting—7/13/89
American Medical Technologists national meeting—7/19/89

Meetings with Organizations or Groups to Develop CLIA Regulations

Department components, including the Center for Disease Control and the Food and Drug Administration
PRISM contractor
College of American Pathologists
American Association of Allergists
American Association of Rheumatologists
House Energy and Commerce staff
Commission on Laboratory Accreditation
American Society of Microbiology
Greater New York Association of Cytotechnologists
Health Industry Manufacturers Association
Technicon laboratory equipment manufacturer
Abbott laboratory equipment manufacturer
American Society for Medical Technology
American Society for Clinical Pathologists
Clinical Laboratory Management Association
National Laboratory Training Network
Commission on Office Laboratory Assessment

Senator COHEN. A lot of attention has been paid to Pap smears, understandably. That no doubt was the impetus for the CLIA 1988 amendments. The law set forth special standards as workload for cytology.

The question I have is do you plan on setting up any special standards for other types of tests such as AIDS or HIV, and if so,

what sort of a grade would you give—for example, I know that New York conducts all antibody testing in its own labs, and it must have a PT score of 100 percent—and what I want to know is what kind of passing score would you accept for AIDS labs?

Dr. WILENSKY. There will be special proficiency tests available for these other areas.

Senator COHEN. What sort of proficiency tests are you going to demand as head of HCFA?

Dr. WILENSKY. I don't know what the answer is. I would be glad to submit that to you for the record, also.

Senator COHEN. All right.

[The information referred to follows:]

PROFICIENCY TESTING

The proficiency testing requirements applicable to laboratories participating in Medicare, Medicaid and licensed under the Clinical laboratory Improvement Act of 1967 were published in final regulations on March 14, 1990, and are effective January 1, 1991. We proposed the same requirements in a Notice of Proposed Rulemaking published May 21, 1990, to apply to all laboratories under the Clinical Laboratory Improvement Amendments of 1988.

Proficiency testing will be required for the majority of the most commonly performed tests where there is scientific consensus on the evaluation of testing performance.

Laboratories that perform anti human immunodeficiency virus (HIV) tests will be required to participate annually in four testing events, each of which would include a minimum of five samples. In each testing event, the laboratory must obtain a score of at least 80 percent for HIV tests. We established the acceptable score at 80 percent because in some weakly reactive tests it may be difficult to distinguish between positive and negative results.

It should be noted that in clinical situations, patients are counseled both before and after HIV testing to discourage any at-risk behaviour, and are notified of the HIV test limitations (i.e., the "window" period during which a person infected with HIV has a low concentration of the virus and the HIV test results may be negative).

Senator COHEN. Another area that has been of particular concern to me is the so-called "deeming" process whereby the Federal Government has delegated responsibility to the various crediting establishments for enforcement authority. That would be the College of American Pathologists and also the Joint Commission on Accreditation of Health Care Organizations.

One of the difficulties I have is that we are delegating more and more responsibility for enforcement to essentially institutions which are more directed toward education than enforcement. Now, under the statutory changes, it makes these accrediting bodies more accountable to HCFA. Have you established any criteria or procedures for approving the various accrediting bodies and what the standards will be for approval and for termination?

Dr. WILENSKY. There are. There are a series of tests that they must meet in order to have "deeming" status. If you would like the technical language, we can also provide you with that.

Senator COHEN. But you have developed the criteria; would you submit those for the record?

Dr. WILENSKY. There is general language on it. I don't think they are in final form. That is again part of the enforcement. But we can at least indicate in general language the kinds of criteria that will be used for the "deeming" authority.

Senator COHEN. Are they going to get specific so we'll know whether or not in fact you have the authority to terminate the accrediting bodies who don't carry out the kinds of enforcement necessary?

Dr. WILENSKY. Yes.

Senator COHEN. If I could go on to the question of cytology now, we are going to hear from Pat Ashton. She conducted a survey with a contract with HCFA, reviewing the practices of several labs which read Pap smears. And of course, she talked about the need to implement these quality standards contained in the final regulations rather quickly.

The question I have is since they only cover 12,000 labs, what about these other labs that read Pap smears? Do they warrant less quality standards in your judgment? The answer, I assume, is "No".

Dr. WILENSKY. No.

Senator COHEN. There is also a question—and here is part of your dilemma, I think, and part of ours, and we are going to have to resolve this, I suppose, working together—on the one hand, we want very high standards, and on the other hand, we make them so strict that you may put out a number of physician labs which may be the only labs available, particularly in rural areas. So it is important that some discretion be exercised in that process as well.

I listened to your testimony very carefully, and I believe you indicated in terms of the cytology proficiency testing standards that it is going to require twice a year proficiency testing, at least one on-site inspection under glass slides——

Dr. WILENSKY. That's correct.

Senator COHEN [continuing.] And we have had information that at least four professional organizations say that that is too strict; that that is unnecessary; that there are not even private organizations who can do that. So there is some suspicion that by setting a standard that is so strict that you don't have any private organizations that can carry it out, that this may be an attempt on the part of HCFA to use that as leverage to force some easing of standards—in other words, force them to back down.

If no one is capable of offering a PT program for cytology, why would you propose it, I guess is the first question. And if they can't do it in the private sector, does HCFA have the capability itself?

Dr. WILENSKY. We don't agree that it cannot be done. We agree that we are pushing and trying to set the proficiency testing at the level that we are setting. The twice-a-year testing incorporated in the statute, that is our advice in terms that that is what the law required. We believe——

Senator COHEN. On-site inspection with——

Dr. WILENSKY. One will be on-site, one will be off-site, unannounced. We believe they are important. They are important to ensure quality, that they were reflecting real, true concern of problems that are out there, and that it will take a little while of getting the slides available, and that while it will have some additional burden, it will not be at the level that has been suggested by some of the organizations that are against it.

Senator COHEN. Just one final point if I could, Mr. Chairman.

We are going to hear, as I indicated, from Pat Ashton, who conducted a number of surveys. And one of the surveys, as a result of that survey, there were two labs that were terminated in the State of California. One of them was inspected by the State Department of Health Services and shut down because of the high error rate and some serious deficiencies.

The question I have is what enforcement action, if any, did HCFA take under CLIA with respect to that particular lab?

Dr. WILENSKY. I would have to find that out. I don't know the answer as to what happened with that particular lab.

Senator COHEN. Was any effort made on the part of HCFA to seek an injunction or attempt to suspend the lab's license?

Dr. WILENSKY. The lab was terminated from Medicare, suspended payment.

Senator COHEN. But the problem is that since there are very few examinations conducted under Medicare, if you terminate them from the Medicare program, it doesn't substantially hurt their business.

Dr. WILENSKY. At the time—and I know this is raising a sore topic, because it is our problem that the other labs aren't in—but at the time, those were the labs under our jurisdiction.

Senator COHEN. Well, weren't you given increased authority under the CLIA Amendments of 1988?

Dr. WILENSKY. Again, my understanding is that until we have rules written that we cannot implement that. I will go check out your interim authority——

Senator COHEN. I thought you had enhanced authority under the Reconciliation Act of 1987 to go to these intermediate types of sanctions, injunctions, suspending licenses. So again the question is because we haven't had the regulations proposed, therefore no action is taken, therefore we delegate it to the State—and you say it is terminated under Medicare, but if they are not being reimbursed under Medicare and still performing Pap smears on a virtually wholesale basis, then we have people going unprotected, when in fact HCFA had the authority to have taken intermediate type of action.

Senator ADAMS. There is an interstate commerce clause added in the 1988——

Dr. WILENSKY. Yes.

Senator COHEN. Thank you.

Senator ADAMS. Senator Mikulski.

Senator MIKULSKI. Dr. Wilensky, I know the hour is drawing late. I would just like to come back to a question I have about enforcement and also the proficiency testing of pathologists and also the proficiency testing of doctors other than pathologists who do laboratory testing.

Let me tell you some facts that your staff will hear if they stay for the hearing—we have kind of a parallel CLIA program in Maryland, and we will be hearing about the Maryland program and some of their early proficiency results. Let me just go through some numbers.

Of the cytologists who were tested for proficiency, 87 percent passed, 13 percent did not; of the pathologists who were tested, 77.5

percent passed, nearly 23–25 percent failed. The cytologists did better than the pathologists.

In the laboratories, 86 percent of the pathologists who employed cytotechs to screen slides passed as part of their pathology test. Of the pathologists who did not employ a cytotech, 50 percent failed.

So I would just point that out to you. What we have here is a problem where pathologists are failing in Maryland more than cytotechs. And then there are other doctors who do laboratory testing, and I wonder also about them. Is this all part of your fit-for-duty analysis?

Dr. WILENSKY. Those are certainly disturbing numbers.

Senator MIKULSKI. But are they part of the enforcement program? What will be done?

Dr. WILENSKY. Everyone who reads a slide has to do proficiency testing, period.

Senator MIKULSKI. Everyone who reads a slide, regardless of who he or she might be.

Dr. WILENSKY. That's right.

Senator MIKULSKI. Well, that is encouraging. And I know that is an extraordinarily big job. I'll just conclude; I just wanted to bring these facts to your attention, because it seems to me that the cytotechnologists are the ones that are really the most reliable part of this situation.

I just want to conclude by saying that in a visit to NIH, where I was asking some questions about cancer, particularly cancer in women, I asked NIH why they didn't spot this problem, because there they are, the National Institutes of Health. And they told me that because they are often more involved with academic situations where laboratories are—say, Johns Hopkins rather than out in Salisbury, MD—that they did not get hold of it. I would hope that we would get a new head of NIH, and I would hope that now that we have a new head of HCFA that we would get NIH to think not only in terms of academic and high-tech research, but that it is a tool for you, when we give you these significant jobs to undertake—and I'm sure there will be more—that you also have a base to turn to other than in some ways the skimpy resources at your own department.

Dr. WILENSKY. Thank you.

Senator ADAMS. Dr. Wilensky, I just have one question. In January, Senators Kennedy, Mikulski and I wrote your predecessor, Mr. Hayes, concerning the promise of emerging technologies in the cytology area. We are going to be questioning in just a moment Ms. Ashton on this. I have been particularly impressed with some of the innovative work done with regard to this even in my home State of Washington. I recently received a response from you that you acknowledged this.

I'd like to put these two letters into the record, and I will without objection do so, and ask that you respond in writing if you will to us, for your comments regarding whether your finalized August 5th regulations and your yet-to-come 1988 regulations regarding this aspect of improvement in cytology, whether those will be inhibited by your regulations or whether they will be allowed under the regulations.

I think you have heard from all four of us of our concern that, individuals reading and doing the pap smear testing are overworking under pressure of getting done for a cheaper price. The results that are coming out of that, which are horrifying in the sense that they are not accurate, is in common terms, as Senator Mikulski said, what we are looking at. So if there is improved technology, if there is a way of making the cytologists' life better and the tests more compact or accurate, we'd like to know whether you are working on that. But we don't want to take any of your time from getting these regulations issued because I think we are appalled about the fact that there are so many labs there, and there are a lot of them you don't know about, and the practice is still going on. That's why we are holding the hearing. We want women to be taking Pap smear tests, and we want them to have confidence in them. If there is anything that I can say today or all of us can say, it is that we want this to happen. It is terribly important. And the purpose of the hearing is not to in any way inhibit that. We want to make it better.

[The documents referred to follow:]

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United States Senate
COMMITTEE ON LABOR AND
HUMAN RESOURCES
WASHINGTON, DC 20510-6300

January 18, 1990

The Honorable Louis B. Hayes
Acting Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Hayes:

As you know, the Health Care Financing Administration is in the process of revising regulations under the Medicare, Medicaid and Clinical Laboratories Improvement Act of 1967 (CLIA). As principal sponsors of the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578) which gave rise to these regulatory revisions, we are writing to clarify Congressional intent regarding the impact of emerging technologies on the workload capacity of these facilities.

It is our understanding that research and development is ongoing regarding improved technological approaches to cytology screening. While the Clinical Laboratory Improvement Amendments of 1988 is silent on this issue, the clear underlying intention of the law is to upgrade the accuracy and reliability of cytology screening. In this regard, there was no intention on the part of the Congress to preclude the development of technology which can assist in achieving this goal.

Section (4)(A) of P.L. 100-578 mandates the setting of the maximum number of cytology slides that any individual may screen in a 24 hour period. Failure to acknowledge some flexibility in the regulatory scheme if new technologies become available would in fact undermine the basic goal of the law. Including workload limitations for cytotechnologists without considering the possible use of more efficient and accurate advanced technologies would discourage the development of such technologies.

We await issuance of the final regulations pursuant to the proposed rule issued on August 5, 1989, and additional proposed regulations to implement P.L. 100-578. As part of that regulatory process, we urge you to take account of the potential beneficial impact of development of new technologies.

We appreciate your immediate attention to our concerns.

Sincerely,

Barbara A. Mikulski

Brock Adams

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

The Honorable Brock Adams
United States Senate
Washington, D.C. 20510

Dear Senator Adams:

I am responding to your letter to Louis B. Hays concerning the development of clinical laboratory regulations. You wrote to clarify Congressional intent about the impact of emerging laboratory technology on these regulations. I apologize for the delay in my response.

I agree that the regulations must not be unnecessarily restrictive or a barrier to the development of advances in technology for improved laboratory testing in any area. The draft regulations currently under review are sufficiently flexible to allow for technological advances that improve the quality of cytology slide examinations. However, we believe that new cytology equipment will need to be evaluated following its development. The purpose of the evaluation will be to determine the appropriate workload limits, instrument calibration, and quality control procedures to be employed by laboratories in order to ensure quality results.

If I can be of further assistance, please let me know. A similar letter is being sent to Senators Mikulski and Kennedy.

Sincerely,

Gail R. Wilensky, Ph.D.
Administrator

Senator ADAMS. Senator Cohen, do you have anything further?

Senator COHEN. A couple of questions. On the cholesterol tests, I think you indicated in your statement that none were in the waivered category; all would be in Category I?

Dr. WILENSKY. Level I.

Senator COHEN. Should all be in Category I? There are about 25 different tests for cholesterol. Are they all treated the same?

Dr. WILENSKY. The cholesterol screen is in Level I.

Senator COHEN. Screening as compared to what?

Dr. WILENSKY. The cholesterol testing for a specific problem. The cholesterol screen test, the interjectory test, is in Level I. Level I specifies tests; waivers specify tests; anything not otherwise specified is Level II.

Senator COHEN. So is it your statement, then, that all of the screening tests conducted by mobile labs will fall in Category I?

Dr. WILENSKY. The screening for cholesterol.

Senator COHEN. Is that what the proposed regulations say?

Dr. WILENSKY. Yes.

Senator COHEN. I would just like to come back to the point made by the chairman, Senator Adams, about a clean slate. One of the difficulties we have had is that we have been here longer than you, and we have been sitting up here for years now. And I remember when Dr. Roper first came as head of HCFA, and I can recall virtually the same thing being said: "Dr. Roper, you are a man of incredible proficiency and accomplishment and integrity, industry, and we are looking forward to you working with this agency to clear up the mess that you have inherited." And indeed it was another province that we had to deal with at that time, but we were willing to say here is a clean slate.

You now have a clean slate in terms of taking over this agency. But it has to do with accountability. We can't have a situation where the agency head keeps changing, and then we have a new person come in and we say, well, we are going to give you a period of time in which to shape things up. There has to be an institutional accountability for the agency itself, so it goes beyond you. You are immediately accountable, and you are in the hot seat right now, but I think ultimately it has to be the agency itself that is held accountable.

That also pertains to the question I asked about "deeming" organizations; that you are going to be "deeming" institutions to provide the enforcement of this statute and the regulations. You are going to hold them accountable. You are now going to have to hold them accountable for their work. And at this point in time there are no specific criteria that have been proposed or developed or even close to being published in terms of how you are going to establish those criteria. And if you don't have those established, you are not going to be able to have enforcement of the tests themselves.

So I think there is a lot of work to be done, and the committee is trying to send a very strong message that we want you to proceed as quickly as you can.

Dr. WILENSKY. There is definitely a lot of work to be done.

Senator ADAMS. Thank you very much, Dr. Wilensky. We appreciate your testimony, and we look forward to seeing you again—in fact, I'm certain we will see you again.

The chair now calls before the committee Panel 3: Patricia Ashton, project director, Specialized Surveys of Cytology Laboratories of the American Society of Cytotechnology, accompanied by Dr. Jack DeBoy, chief, Division of Laboratory Licensure, Certification and Training, Maryland State Department of Health and Mental Hygiene.

Welcome. We will be pleased to receive your statements. You may summarize them or give them—we have copies, so that if you wish to work from them, you can.

Ms. Ashton, we look forward to hearing your testimony, and then Dr. DeBoy, we will turn to you.

Ms. Ashton, welcome.

STATEMENTS OF PATRICIA ASHTON, PROJECT DIRECTOR, SPECIALIZED SURVEYS OF CYTOLOGY LABORATORIES CONTRACT, AMERICAN SOCIETY OF CYTOTECHNOLOGY; AND DR. JACK DEBOY, CHIEF, DIVISION OF LABORATORY LICENSURE, CERTIFICATION AND TRAINING, MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Ms. ASHTON. Thank you, Mr. Chairman, and good morning to you as well as Senator Cohen.

I am Pat Ashton, a cytotechnologist, legislative consultant to the American Society for Cytotechnology, and the project director for the Health Care Financing Administration-awarded contract to perform specialized surveys of cytology laboratories.

At your invitation, I am here today to present the summary of the findings from the first year and a half of the contract.

In June of 1988, Health Care Financing Administration awarded the contract to the American Society for Cytotechnology in response to its ongoing concerns about the quality of cytology services in this country and in order to gain the expertise of cytotechnologists and pathologists in evaluating cytology laboratories.

An important difference between the surveys conducted under this contract and the typical Medicare/CLIA 1967 surveys is that the cytotechnologists and pathologists performing these surveys microscopically evaluate a sample of cases previously reported by the laboratory in order to assess

the quality of the preparations and stains and to assess the accuracy of the diagnoses.

In the first year of the contract, surveys were conducted in 18 laboratories. At least one laboratory from each of the large national chains was surveyed, as well as several of the other laboratories identified in the *Wall Street Journal* articles of February and November 1987.

The contract with the ASCT was extended in June of 1989 for a second year. At present, surveys of an additional 13 laboratories have been completed. Laboratories from 9 of 10 HCFA regions have been surveyed. The annual cytology case volumes ranged from 2,000 to 807,000. Twenty-nine of the 31 laboratories have been independent, while the remaining two were located in hospitals.

During the first year of the contract, eight laboratories were not in compliance with one or more of the seven Medicare conditions for coverage. In the second year of the contract, four laboratories have not been in compliance with one or more conditions.

The identification of a condition-level deficiency indicates that the laboratory has a significant number of problems in the particular condition identified, and the problems must be satisfactorily corrected within 45 days in order for the laboratory to continue its participation in the Medicare and Medicaid programs.

During the first year of the contract, two laboratories were terminated from the Medicare/Medicaid programs because they represented an immediate and serious threat to patient health and safety. They were put on the fast-track termination, which provides the laboratories 23 days from the end of the survey in which to present documentation that they have corrected their serious problems.

One of these laboratories subsequently went out of business; the other changed ownership, corrected its deficiencies, applied for reinstatement in Medicare and after two more surveys were conducted to document correction of all problems, has been readmitted to the Medicare program.

In the second year, one laboratory has been terminated from Medicare under the immediate and serious threat termination procedure subject to appeal.

The majority of the deficiencies identified in the surveyed laboratories relate to management, recordkeeping and quality control. Ten of the laboratories surveyed have not had acceptable quality control programs in operation to ensure the accuracy of their diagnostic reports. The current regulations require that labs have an acceptable quality control program in place, covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision and detection of error. The minimal requirements specifically for cytology require that 10 percent of cases interpreted to be in the benign categories by personnel not possessing supervisory qualifications be reviewed by either a supervisory cytotechnologist, or a technical supervisor, who is the pathologist, and that all gynecologic smears interested to be in suspicious or positive categories in all nongynecologic cases must be reviewed by the pathologist/technical supervisor.

Compliance with these minimal requirements frequently represented the extent of the quality control program in place in a laboratory. For laboratories in which all of the cytotechnologists meet supervisory qualifications, which is having 4 years' experience, a review of 10 percent of the negatives is not required, and these laboratories may feel that it is not necessary to have an overall quality control program in place to monitor performance. But even the current regulations do require such a program.

On the other hand, a number of the laboratories surveyed had excellent, well-documented, effective quality control programs and had a very good handle on how well their staffs were performing.

Of great concern to HCFA and to us was the finding that a significant number of the laboratories did not appear to provide feedback to their staff when interpretive errors were identified during quality control reviews. The essential aspect of quality control re-

screening of an individual's cases is that any errors identified during the re-screen should be reviewed with the individuals responsible for the misdiagnoses. These laboratories performed the required re-screening, but did not complete the cycle of providing their staff with feedback about their errors. In cases where severe discrepancies were found, they usually did review them with a staff member, but not always in the case of minor discrepancies.

Eighteen laboratories have had discrepancies between the laboratories' report of a specimen in the survey team's interpretation of that same specimen. Significant discrepancies are defined as ones which could affect patient care. Specifically, they are defined on individual cases as either a negative diagnosis had been reported by the laboratory, while the survey team determined the case to be unsatisfactory for interpretation, or a negative diagnosis had been made, and the survey team found evidence of Human Papilloma virus effect, dysplasia or worse. All cases of this nature identified by survey team cytotechnologists were reviewed by either the survey team pathologist, the laboratory's pathologist or both before the laboratory was cited for reporting such a case in error. Laboratories were requested to obtain appropriate follow-up information on these cases.

It must be noted that the diagnostic discrepancies described above represent errors found in only a very limited number of laboratories providing services in this country, and their occurrence within these labs was, in most cases, limited as well. Every cytology laboratory makes diagnostic errors. It is just part of standard operating procedures and unavoidable. And since no national standards currently exist concerning what is acceptable performance, these statistics cannot be extrapolated to cytology laboratories as a whole or used to compare one laboratory with another.

In our first-year report, ASCT made several recommendations to Health Care Financing Administration for ways to improve the quality of cytology services in this country as well as for improving the quality of their own assessment of laboratories providing these services.

The first recommendation and the one about which this hearing most directly relates is that HCFA should implement, with some modifications, the revised Federal requirements for cytology as proposed in August of 1988. We concluded that the implementation of most of the proposed standards would improve the overall quality of cytology services in this country. Experience in the second year of the contract has not changed our conclusion.

The enactment of CLIA 1988 has made mandatory several of the standards which HCFA had proposed in their August 5th rules. These measures—workload limits for individuals examining cytology specimens, re-screening requirements, periodic evaluation of the proficiency of individuals involved in screening and interpreting cytological preparations, and a requirement for the periodic inspection of cytology services by persons capable of evaluating the quality of these services—will greatly improve the quality of care delivered by cytology labs.

It must be recognized, however, that improved quality control and quality assurance will add significantly to the cost of a Pap

smear, cause delays in reporting, and may restrict patient access to this service.

The second recommendation was that on-site reviews of diagnostic slides from the laboratory become a part of the routine survey process. The study has demonstrated that this is an effective means of assessing the validity of the laboratory's results. By reviewing slides and reports, experienced and qualified surveyors can more easily identify areas in a laboratory's operation which need improvement.

Recommendation 3 was to implement the Bethesda system for reporting cervical/vaginal cytologic diagnoses. The Bethesda system was developed in 1989 and published in August of 1989 by a consensus of laboratorians and clinicians in an attempt to standardize the reporting of Pap smears. The professional community concluded that a uniform system to replace all of the many modifications of the original Papanicolaou class system should be adopted, and the Bethesda system is gaining in acceptance and popularity.

All 18 laboratories surveyed during the first year of the contract used the Papanicolaou class system, and each laboratory used it differently. This certainly does not provide for good communication between patients, physicians and laboratories.

Recommendation 4 was that a panel of experts in diagnostic cytology, including both cytotechnologists and pathologists, be convened to develop standards of practice for performance of cytology services which will be acceptable to and attainable by the laboratories in this country.

Areas in which professional standards are needed include. Determination of criteria for an adequate sample for Pap smears under various physiologic and diagnostic conditions; appropriate fixation and staining procedures or techniques; acceptable levels of performance for cytotechnologists and pathologists, and definitions of and acceptable rates for false-negatives, false-positives, or errors.

The news media would have us believe that since CLIA 1988 has yet to be implemented, the women of this country are no better off than they were 2 years ago as far as Pap smear reports are concerned. This has not been our observation. Many laboratories began making significant changes in their quality control procedures as soon as the August 5th proposed rule was published.

In anticipation of CLIA 1988, and in response to the unfavorable press, some have imposed their own workload restrictions and have changed the way in which they compensate their cytotechnologists.

All of this advance preparation does not mean, however, that CLIA 1988 and the final rule are not needed. They most certainly are. Our study shows that there still are problems existing in cytology laboratories, and unfortunately it will take the weight of regulation and continuous monitoring to bring about these necessary changes.

The ASCT is pleased to hear from Dr. Wilensky this morning that the proposed rule will be published in the *Federal Register* next week, and we, as you, are anxiously awaiting the publication of the proposed rule to implement CLIA 1988 so that laboratories will finally know for sure what will be expected of them, so that they can officially respond to the Health Care Financing Administration with their concerns and suggestions.

Thank you very much for your continued interest, and I would be happy to answer any questions.

Senator ADAMS. Thank you, Ms. Ashton.

[The prepared statement of Ms. Ashton follows:]

STATEMENT OF

PATRICIA R. ASHTON, A.B., SCT(ASCP)

LEGISLATIVE CONSULTANT, ASCT
and
PROJECT DIRECTOR,
SPECIALIZED SURVEYS OF CYTOLOGY LABORATORIES CONTRACT

The Health Care Financing Administration (HCFA) has long been interested in improving the quality of cytology services in this country as well as its own surveys of cytology laboratories. In December of 1986, well before CLIA'88 and the Wall Street Journal articles, the HCFA prepared and published in Commerce Business Daily, an RFP, Request for Proposal, to perform specialized surveys of cytology laboratories. There were no satisfactory proposals submitted in response to that request. HCFA re-published its Request for Proposal in July of 1987 and received three proposals for consideration. In June of 1988, the contract to perform the specialized surveys of selected cytology laboratories was awarded to the American Society for Cytotechnology.

The current contract award followed a 1981 award, HCFA-81-0618, to the American Society of Cytology "to recommend guidelines and procedures for the survey of cytology facilities and for the evaluation, regulation and improvement of the quality of cytology services provided to beneficiaries in the Medicare and Medicaid programs." The project director for the current contract was a primary author of the report submitted to HCFA in 1982 entitled "Recommendations to Health Care Financing Administration: Guidelines for Inspecting Cytopathology Laboratories."

The purpose of the 1988 contract was to assess the validity of cytology laboratory results by having cytotechnologists and consultant cytopathologists perform surveys of selected cytology laboratories using the current Federal regulations and survey documents and more importantly, to have these individuals evaluate a sample of patient slides for quality of preparation as well as diagnostic accuracy. The entire report from the first year of the contract,

prepared for the HCFA, will be made a part of the record of these hearings.

During the first year of the contract, 23 surveys were scheduled in 18 different laboratories. Three laboratories were surveyed twice, two for extensive onsite rescreening of diagnostic material and one to determine whether the laboratory should be reinstated into the Medicare program. Upon arrival at two laboratories, it was found that they no longer provided cytology services and therefore are excluded from the results discussed below. 17 of the laboratories were independent laboratories and one was located in a hospital. Laboratories were selected for review by HCFA's Central Office based on a request for additional assistance or in response to a specific complaint about the laboratory. At least one laboratory from each of the largest national chains (SmithKline Bio-Science Clinical Labs, Metpath Clinical Laboratories, Roche Biomedical Laboratories, National Health Laboratories) were surveyed as well as several of the laboratories identified in the Wall Street Journal articles of February and November, 1987.

The contract with the American Society for Cytotechnology (ASCT) was extended in June of 1989 for a second year. At the present time, surveys of an additional 13 laboratories have been completed. Three of the laboratories have been surveyed twice; one to verify compliance with the laboratory's previously submitted plan of correction and the other two for more extensive on-site evaluation. Two of the 13 laboratories were re-surveys of laboratories originally examined during the first year of the contract; one for readmission into the Medicare program and one to verify compliance with its submitted plan of correction. Twelve of the 13 laboratories were independent and 1 was located in a hospital. Laboratories from 9 of 10 HCFA regions have been surveyed. (Exhibit IA & IB) The annual cytology volume of the laboratories ranged from a low of 2,000 to a high of 807,000. (Exhibit

IIA & IIB) .Survey teams consisted of from two to seven cytotechnologists, the exact number determined by the annual cytology volume of the laboratory, and a consultant cytopathologist. Surveys lasted 3-5 days, depending on the size of the laboratory, and a consultant cytopathologist, the survey team leader, performed the routine Medicare/CLIA'67 survey, while the remaining cytotechnologist[s] spent their time reviewing the actual diagnostic material. The consultant cytopathologist was not always on site in the laboratory. The decision as to whether the pathologist needed to be present at the survey was based upon the number and nature of deficiencies identified by the survey team cytotechnologists. The pathologists were "on-call" and were prepared to come to the laboratory if necessary. They were kept abreast of survey findings by the team leader.

Slides and accompanying reports to be reviewed by the survey team cytotechnologists were selected at random based on the way in which the laboratory filed its slides and reports. Due to the wide variety of systems employed by laboratories to accession and file slides and reports, the same method could not be used in each laboratory. The teams evaluated a minimum of 50 cases from each laboratory and attempted to evaluate cases previously interpreted by each cytotechnologist and pathologist. The cases were evaluated for quality of preparation, staining and coverslipping and for diagnostic accuracy. If survey team cytotechnologists identified any cases in which they did not concur with the laboratory's original diagnosis, the cases were reviewed by other members of the survey team. If the discrepancies were of a degree which would affect patient care, these cases were reviewed by the survey team cytopathologist or with the laboratory's pathologist (technical supervisor) responsible for cytology.

FINDINGS

During the first year of the contract, 8 of the laboratories were not in compliance with one or more of the Medicare Conditions for Coverage. In the second year of the contract, four laboratories were not in compliance with one or more Medicare Conditions for Coverage. The identification of a Condition level deficiency indicates that the laboratory has a significant number of deficiencies in the particular Condition identified. The significance of Condition level deficiencies is that the identified problems must be satisfactorily corrected within 45 days in order for that laboratory to continue its participation in the Medicare/Medicaid programs. In addition, an on-site revisit by the State Surveyor may be necessary to verify correction of deficiencies.

The Conditions of Laboratory Director, Supervision, Technical Personnel, Management and Quality Control were NOT MET in one laboratory; Laboratory Director, Supervision, Management and Quality Control in another laboratory; Laboratory Director, Management and Quality Control in four laboratories; Supervision, Management and Quality Control in one laboratory; Supervision alone was NOT MET in one laboratory; Management alone was NOT MET in three laboratories and one hospital was not in compliance with the Condition of Participation for Laboratory services.

During the first year of the contract, two laboratories were terminated from participation in the Medicare/Medicaid programs because they represented an immediate and serious threat to patient health and safety. The laboratories were put on "fast track" termination which provides the laboratory 23 days from the last day of the survey to present a credible allegation

documenting correction of the deficiencies which caused the immediate and serious threat to patient health and safety. One of these laboratories subsequently went out of business; the other changed ownership, corrected its deficiencies, applied for reinstatement in Medicare, and after 2 surveys were conducted documenting correction of all problems, has been readmitted to the Medicare program. In the second year of the contract, one laboratory has been terminated from the Medicare program under the immediate and serious threat termination procedures, subject to appeal.

Exhibit 3 lists the deficiencies identified and the number and percentage of laboratories in which they were found. The pattern of deficiencies established during the first year of the contract has continued into the second. That is, the majority of the deficiencies identified relate to laboratory management, record keeping and general quality control. All laboratories except one did not have accurate, complete procedure manuals available. A large percentage of laboratories (83.87%) did not maintain adequate quality control records documenting feedback to cytotechnologists when interpretive errors were identified during quality control reviews. The essential aspect of quality control rescreens of an individual's cases is that any errors identified during the rescreens are reviewed with the individual responsible for the misdiagnosis. Almost two-thirds of the laboratories (61%), lacked documentation that the "suspicious" and positive smears were reviewed and the final reports signed by the pathologist (technical supervisor) to reflect that they were verified for accuracy. In some instances, the reports which were sent to the physician clients were signed, but a duplicate signature copy was not maintained in the laboratory; in other instances, the reports were generated from a computer and neither the original nor the duplicate reports reflected a pathologist's review, verification or signature.

Approximately one/third of the laboratories surveyed have not had acceptable quality control programs in operation to insure the quality of their diagnostic reports. One of the standards under the Condition of quality control states "Provision is made for an acceptable quality control program covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision, and detection of error." The minimal requirements specifically for cytology require that 10% of cases interpreted to be in the benign categories by personnel not possessing supervisory qualifications be reviewed by a supervisory cytotechnologist or a technical supervisor (pathologist); that all gynecologic smears interpreted to be in "suspicious" or positive categories and all non-gynecologic smears be reviewed by the technical supervisor (pathologist); and that all smears be retained for not less than two years. Compliance with these minimal requirements frequently represented the extent of the quality control program in place in a laboratory. For laboratories in which all the cytotechnologists meet supervisory qualifications (4 years experience), a review of 10% of the negatives is not required; and these laboratories may feel that it is not necessary to have an overall quality control program in place to monitor performance, but the regulations do require an ongoing evaluation program.

Twenty-four of thirty-one laboratories were found to have significant discrepancies between the laboratory's report of a specimen and the survey team's interpretation of that same specimen. Significant discrepancies were defined as ones which could affect patient care. Specifically, significant discrepancies on individual cases were identified as follows: (1) a diagnosis (negative) had been reported by the laboratory while the survey team determined the case to be unsatisfactory for interpretation and (2) a negative diagnosis had been reported by the laboratory and survey team found evidence of Human Papilloma virus effect, dysplasia or

worse. All significant cases of this nature identified by survey team cytotechnologists were reviewed by either the survey team pathologist, the laboratory's pathologist or both before the laboratory was cited for reporting such a case in error. On the survey report sent to the laboratory, significant case discrepancies were identified, and the laboratory was requested to obtain appropriate follow-up on these cases.

It must be noted that the diagnostic discrepancies described above represent discrepancies found in only a limited number of laboratories providing cytology services in this country and their occurrence within individual laboratories was, in most cases, limited. Every cytology laboratory has made diagnostic errors and since no national standards exist concerning acceptable performance, error rates, false-negative or false-positive percentages, these statistics cannot be extrapolated to cytology laboratories as a whole or in comparing one laboratory with another laboratory. However, the findings do provide the laboratories surveyed with specific information about areas in which performance must be improved.

RECOMMENDATIONS

At the end of the first year of the contract, the American Society for Cytotechnology (ASCT) proposed several recommendations to the (HCFA) for improving the quality of cytology services in this country as well as for improving the quality of their own assessment of these laboratories. The first recommendation and the one about which this hearing most directly relates is that HCFA should implement the revised Federal requirements for cytology as proposed in the Notice of Proposed Rulemaking of August 5, 1988. We concluded that the implementation of the proposed standards, with modifications, would improve the overall quality

of cytology services in this country. Experience in the second year of the contract has not changed our recommendation. The enactment of CLIA'88 has made mandatory a number of the standards which HCFA had proposed in their August 5,1988 NPRM. These measures, workload limits for individuals examining cytology specimens, rescreening requirements, periodic evaluation of the proficiency of individuals involved in screening of interpreting cytological preparations, and a requirement for the periodic inspection of cytology services by persons capable of evaluating the quality of cytology services will also help improve the quality of care delivered by cytology laboratories.

It must be recognized, however, that improved quality control and quality assurance will add significantly to the cost of a Pap smear, cause delays in reporting, and may restrict patient access to this service.

The second recommendation was that on-site reviews of diagnostic slides from the laboratory become a part of the routine survey process. The study has demonstrated that this is an effective means of assessing the validity of the laboratory's results. By reviewing the slides and reports, experienced and qualified surveyors may be able to identify areas in a laboratory's operation which need improvement. With the current shortage of qualified cytotechnologists to perform the routine work in the cytology laboratories, it will be equally difficult to find qualified cytotechnologists interested in performing these surveys. Since CLIA'88 requires biennial surveys of laboratories, one option is for cytology laboratories to be evaluated in this way every other time or once every four years. The intervening surveys could be conducted by the state surveyors with assistance from consultant cytotechnologists and pathologists if needed.

A second option is to have all laboratories providing cytology services be surveyed, including review of diagnostic material, at least once. In subsequent years, appropriately trained state surveyors would perform the biennial surveys and could have the option of requesting consultant cytotechnologists' and pathologists' assistance, if necessary.

Recommendation 3 is to implement the Bethesda system for reporting cervical/vaginal cytologic diagnoses. The Bethesda system was developed in 1989 by a consensus of laboratorians and clinicians in an attempt to standardize the reporting of Pap smears. The professional community has concluded that a uniform system to replace all of the many modifications of the original Papanicolaou class system should be adopted and the Bethesda system is gaining in acceptance and popularity. All 18 laboratories surveyed during the first year of the contract used the Papanicolaou class system and each laboratory used it differently. This does not provide for good communication between patients, physicians and laboratories.

Recommendation 4 is that a panel of experts in diagnostic cytology, including both cytotechnologists and pathologists be convened to develop standards of practice for performance of cytology services which will be acceptable to and attainable by the laboratories in this country. Areas in which professional standards are needed include: 1) determination of criteria for an adequate sample for Pap smears under various physiologic and diagnostic conditions; 2) appropriate fixation and staining procedures or techniques; 3) acceptable levels of performance for cytotechnologists and pathologists and 4) definitions of and acceptable rates for "false negatives," "false positives," or "errors."

OBSERVATIONS AND COMMENTS FROM LAST TWO YEARS

Although the news media would have us believe that since CLIA'88 has yet to be implemented, the women of this country are no better off than they were two years ago as regards Pap smear testing. This has not been our observation. Many laboratories have seen the handwriting on the wall and have made significant improvements in their operations. The large independent laboratories, particularly those which are part of national chains and have a presence in Washington, are very familiar with what the revised proposed regulations and CLIA'88 may require and have begun to implement many of the quality control requirements if they were not already implementing them. Some have imposed their own workload restrictions and/or changed the way in which they compensate their cytotechnologists and have generally attempted to improve their service to patients.

The professional organizations and news services serving the laboratory community have publicized widely any information which they have obtained about either the HCFA final rule or the proposed CLIA'88 regulations. Thus the laboratories have had advance notice about what to expect and interested laboratories should be well informed and have begun to make changes in their operations, if necessary.

All this warning and advance preparation does not mean, however, that CLIA'88 and the final rule are not needed. They are, and the ASCT hopes that the final rule and the CLIA'88 NPRM will soon be published in the Federal Register so that interested parties will finally know what will be expected of them and so that they can officially respond to HCFA about their content.

EXHIBIT I-A

NUMBER OF LABORATORIES SURVEYED BY HCFA REGION
(1ST YEAR OF CONTRACT)

REGION	NO. OF LABS	% OF LABS
I	1	5.56%
II	2	11.11%
III	2	11.11%
IV	4	22.22%
V	2	11.11%
VI	2	11.11%
VII	0	0.00%
VIII	1	5.56%
IX	3	16.67%
X	1	5.56%

EXHIBIT I-B

NUMBER OF LABORATORIES SURVEYED BY HCFA REGION

(COMPLETED SURVEYS, YEAR 2 OF CONTRACT)
EXHIBIT 2-B

REGION	NO. OF LABS	% OF LABS
I	1	7.69%
II	1	7.69%
III	1	7.69%
IV	2	15.38%
V	2	15.38%
VI	2	15.38%
VII	0	0.00%
VIII	0	0.00%
IX	2	15.38%
X	2	15.38%

EXHIBIT II-A

NUMBER OF LABORATORIES SURVEYED BY ANNUAL VOLUME
(1ST YEAR OF CONTRACT)

NUMBER OF CASES/YEAR	NO. OF LABS	% OF LABS
<10,000	1	5.56%
10 - 50,000	5	27.78%
50 - 100,000	4	22.22%
100 -150,000	2	11.11%
150 - 200,000	1	5.56%
200 - 300,000	1	5.56%
>500,000	4	22.22%

EXHIBIT II-B

NUMBER OF LABORATORIES SURVEYED BY ANNUAL VOLUME

(COMPLETED SURVEYS, YEAR 2 OF CONTRACT)

NUMBER OF CASES/YEAR	NO. OF LABS	% OF LABS
<10,000	1	7.69%
10 - 50,000	4	30.77%
50 - 100,000	4	30.77%
100 - 150,000	1	7.69%
150 - 200,000	1	7.69%
200 - 300,000	1	7.69%
>500,000	1	7.69%

EXHIBIT III-A

DEFICIENCIES IDENTIFIED IN LABORATORIES SURVEYED

FINDINGS FROM FIRST YEAR OF CONTRACT

E-TAG #	DEFICIENCY	# OF LABS	% OF LABS
026	CONDITION-LABORATORY DIRECTOR (405.1312)	4	22.22%
027	Lab. Director, Administration	5	27.78%
028	CONDITION-SUPERVISION (405.1313)	1	5.56%
029	Technical Supervision	0	0.00%
030	General Supervision	2	11.11%
055	CONDITION-TECHNICAL PERSONNEL (405.1315)	0	0.00%
056	Technologist's Duties	0	0.00%
061	Personnel Policies	4	22.22%
062	CONDITION-MANAGEMENT (405.1316)	8	44.44%
063	Procedure Manual	12	66.67%
064	Adequacy of Space & Facilities	8	44.44%
065	Storage of Chemicals	6	33.33%
068	Fire & Safety Precautions	12	66.67%
071	Disinfection Techniques	5	27.78%
072	Disposal Policies	4	22.22%
075	Examination and Reports	1	5.56%
076	Reference Specimens	1	5.56%
077	Specimen Records	11	61.11%
078	Data for Test Performed	5	27.78%
079	Directors Responsibility for report	13	72.22%
080	Copies/Records Maintained	9	50.00%
083	Pertinent Normal Ranges Available	4	22.22%
084	List of Analytical Methods Maintained	6	33.33%
085	Ref. Lab Meets Conditions	7	38.89%
086	CONDITION-QUALITY CONTROL(405.1317)	5	27.78%
087	Quality Control-General	7	38.89%
088	Preventive Maintenance	13	72.22%
089	Adequacy of Equipment & Methods	12	66.67%
090	Labeling of Reagents & Solutions	17	94.44%
091	Availability of Current Manuals	18	100.00%
093	Maintenance & Availability of QC	14	77.78%
094	Adequate Collection Methods	6	33.33%
095	Quality Control, Methodologies	6	33.33%
267	10% Rescreen Performed	3	16.67%
268	Doc. Rev. Abnormals by Tech. Sup.	11	61.11%
269	Doc. of Non-Gynecologic Review	4	22.22%
270	Non-manual Methods	1	5.56%
271	Proper Slide Retention	2	11.11%
272	QC Methodologies-Cytology	6	33.33%
			0.00%
			0.00%

EXHIBIT III-B

DEFICIENCIES IDENTIFIED IN LABORATORIES SURVEYED

FINDINGS FROM COMPLETED SURVEYS (13) IN SECOND YEAR

E-TAG #	DEFICIENCY	# OF LABS	% OF LABS
026	CONDITION-LABORATORY DIRECTOR (405.1312)	2	15.38%
027	Lab. Director, Administration	2	15.38%
028	CONDITION-SUPERVISION (405.1313)	3	23.08%
029	Technical Supervision	1	7.69%
030	General Supervision	3	23.08%
055	CONDITION-TECHNICAL PERSONNEL (405.1315)	1	7.69%
056	Technologist's Duties	1	7.69%
061	Personnel Policies	2	15.38%
062	CONDITION-MANAGEMENT (405.1316)	3	23.08%
063	Procedure Manual	1	7.69%
064	Adequacy of Space & Facilities	3	23.08%
065	Storage of Chemicals	4	30.77%
068	Fire & Safety Precautions	7	53.85%
071	Disinfection Techniques	2	15.38%
072	Disposal Policies	1	7.69%
075	Examination and Reports	2	15.38%
076	Reference Specimens	0	0.00%
077	Specimen Records	6	46.15%
078	Data for Test Performed	4	30.77%
079	Directors Responsibility for report	11	84.62%
080	Copies/Records Maintained	5	38.46%
083	Pertinent Normal Ranges Available	3	23.08%
084	List of Analytical Methods Maintained	5	38.46%
085	Ref. Lab Meets Conditions	5	38.46%
086	CONDITION-QUALITY CONTROL(405.1317)	2	15.38%
087	Quality Control-General	3	23.08%
088	Preventive Maintenance	7	53.85%
089	Adequacy of Equipment & Methods	7	53.85%
090	Labeling of Reagents & Solutions	6	46.15%
091	Availability of Current Manuals	12	92.31%
093	Maintenance & Availability of QC	12	92.31%
094	Adequate Collection Methods	2	15.38%
095	Quality Control, Methodologies	4	30.77%
267	10% Rescreen Performed	2	15.38%
268	Doc. Rev. Abnormals by Tech. Sup.	8	61.54%
269	Doc. of Non-Gynecologic Review	2	15.38%
270	Non-manual Methods	0	0.00%
271	Proper Slide Retention	2	15.38%
272	QC Methodologies-Cytology	1	7.69%

EXHIBIT 4

LABORATORIES SURVEYED AND DEFICIENCIES CITED

NAME AND ADDRESS OR LABORATORY	E-TAGS CITED
1. Bio-Medix Clinical Lab., Inc. Baltimore, Maryland	061,062,068,078,085,088,089,091 093,094,268
2. National Cytolab, Inc. Harvey, Illinois	026,027,061,062,063,065,068,071 076,077,078,079,080,083,084,085, 086,087,088,089,090,091,092,093 095,267,268,272
3. Diagnostic Laboratories, Inc. Palm Beach Gardens, Florida	062,063,064,065,068,071,072,077 079,083,080,089,090,091,093,094 268
4. Northwest Laboratories, INc. Oklahoma City, Oklahoma	026,027,030.062,063,064,071,072 078,079,080,083,084,085,086,087 088,089,090,091,093,094,095,267 271,272
5. Medlab	077,078,079,088,090,091,093,268 269
6. Western Pathology Med. Grp. Dublin, California	077,080,084,089,090,091,268,269
7. Planned Parenthood of Rocky Mountain, Aurora, Colorado	085,088,089,090,091,093,268
8. Bioran Medical Laboratory Cambridge, Ma.	064,065,090,091
9. Path. and Cyto. Lab., Inc. Lexington, Kentucky	026,027,062,063,064,065,068,077 079.080,086,087,088,089,091,093 095,272
10. Central Pathology Svcs. Med. Grp. Tarzana, California	026,027,061,062,063,064,065,068 071,077,078,079,080,083,084,085 086,087,088,089,090,091,093,094 095,268,269,272
11. Cancer Screening Services North Hollywood, California	063,065,075,077,079,080,087,088 090,091,268,269
12. Rancocas Hospital Laboratory Willingboro, New Jersey	061,063,068,088,089,090,091,093 094,268

13.	Roche Biomedical Labs., Inc. Tucker, Georgia	028,030,062,063,064,068,072,077 079,080,085,086,087,088,089,090 091,093,095,267,279,272
14.	Tampa Pathology Laboratory Tampa, Florida	077,088,092,093,095
15.	National Health Labs., Inc. Vienna, Virginia	063,068,071,079,090,091
16.	Chicago Department of Health Chicago, Illinois	027,063,064,068,077,079,080,089 090,091,271
17.	International Can. Screen. Lab. San Antonio, Texas	062,063,064,068,077,079,080,089 090,091,093,094,268
18.	Metpath Clinical Laboratories Teterboro, New Jersey	063,068,072,077,079,089,090,091 093,268
19.	Continental Bio-Clinical Labs Grand Rapids, Michigan	065,068,071,079,089,090,091,093
20.	National Health Laboratories Winston-Salem, N.C.	065,068,077,079,084,091,268
21.	National Cytolab Harvey, Illinois	079,091,093
22.	Reference Pathology Lab Nashville, Tennessee	085,091,093,268,269
23.	CML-D'Ambruoso Laboratory Waterbury, Connecticut	026,027,028,029,062,075,077,078 079,080,085,086,087,088,089,091 093.095,268,271
24.	New Mexico Scientific Lab Div. Albuquerque, New Mexico	028,030,078,079,085,088,089,090 091,093,095,267,268
25.	Universal Diagnostic Laboratory Brooklyn, New York	061,068,079,080,084.088,091,093
26.	International Cancer Screen. Lab San Antonio, Texas	077,079
27.	Our Lady of Lourdes Hospital Pasco, Washington	062,075,077,078,083,084,085,087 088,089,090,091,093
28.	Northwest Cytolab Seattle, Washington	065,068,077,079,083,084,088,090 091,093,094,095,268
29.	Yosemite Pathology Med. Grp. Modesto, California	064,068,079,080,085,089,091,093
30.	Metpath of Arizona Phoenix, Arizona	064,068,080,093,268
31.	Cancer Cytology Medical Lab. Rockville, Maryland	026,027,028,030,055,056,061,062 063,064,065,068,071,072,077,078 079,080,083,084,086,087,088,089 090,091,093,094,095,267,268,269 271,272

Senator ADAMS. Dr. DeBoy.

Dr. DEBOY. Thank you, Mr. Chairman, members of the committee.

I am John M. DeBoy, a Doctor of Public Health and Chief of the Division of Laboratory Licensure, Certification and Training in the Department of Health and Mental Hygiene for the State of Maryland.

I appear before you today to present data that will show a continuing need in this country for proficiency testing programs to test all cytopathology laboratories, and the pathologists and cytotechnologists employed in screening and evaluating Papanicolaou smears for cervical cancer.

In January of 1988, this committee concluded hearings on problems affecting cancer detection in women by making a forceful call for increased laboratory regulation at both State and Federal levels. The Maryland General Assembly accepted this Congressional challenge by passing a law that greatly expands the regulation of cytopathology laboratories. This Maryland law, which took effect July 1, 1988, mandated specific technical standards for medical laboratories offering cytopathology services and required that all cytopathologists and cytotechnologists participate in a State-operated proficiency testing program.

In cytopathology, the only type of proficiency testing program that can test individuals reliable and fairly is one providing test conditions that closely match a cytopathology laboratory's daily work routine. Maryland developed such a program by requiring that the test materials be actual patient Pap smears, that they be hand-carried to the laboratory and diagnosed on-site, and that the testing be conducted under the supervision of a regulatory official.

In just under 24 months, the Maryland State Department of Health and Mental Hygiene, with much help from a panel of expert Maryland cytotechnologists and cytopathologists, designed this type of proficiency testing program, drafted and promulgated necessary regulations, obtained and evaluated patient testing materials, and conducted pilot proficiency tests.

Maryland's new regulatory program for cytopathology laboratories was fully implemented as of November 1989, and its first official proficiency testing cycle was begun January 1, 1990.

Mr. Chairman, I will not present some actual cytopathology proficiency test statistics obtained between January and August of 1989 when Maryland conducted its pilot tests on 72 laboratories. Twenty-six percent of these 72 laboratories failed the test. The 19 laboratories that failed accounted for 14 percent of the approximately 1.1 million Pap smear slides diagnosed in Maryland during 1989. Seventy-nine percent of the laboratories that failed read fewer than 10,000 slides per year. Sixty-eight percent read fewer than 5,000 slides per year.

The tally of test results showed that 22.5 percent of 129 pathologists failed and that 12.3 percent of 106 cytotechnologists failed. Only 39 percent of the pathologists who did not employ cytotechnologists passed, while 88.6 percent of pathologists who did employ cytotechnologists passed.

This represents a 50 percent higher failure rate among cytopathologists who did not employ a cytotechnologist. The State has

showed that the smaller laboratories, especially those consisting of a single cytopathologist, are more likely to fail proficiency testing. This means that any cytology proficiency testing program must make a special effort to identify and routinely test these smaller laboratories.

A review of individual test slide diagnoses made by the cytopathologists showed that 5 percent of all diagnoses were significant undercalls or false-negatives. Just under one percent were significant overcalls or false-positives. Persons taking a proficiency test can be expected to perform at their best. When cytopathologists diagnose a 5 percent false-negative rate in proficiency tests, it is fair to suggest that the false-negative rate in routine practice may be substantially higher.

In 1971 and 1972, New York State's pilot test failed 46 percent of New York's laboratories. In 1989, Maryland's pilot test failed 26 percent of its laboratories. The proportion of cytopathologists who failed initial tests during New York's 1972 and 1973 testing cycle was 33 percent. In Maryland in 1989, it was 22.5 percent. The past 18 years were heavily regulated ones for medical laboratories in this country; but this seems to have had little effect on many individuals' personal proficiency in diagnosing Pap smears.

In New York, the failure rate for a cycle's initial test has remained around 20 percent for the last 10 years. The percentage of cytopathologists in New York who fail a second test and require retraining has stayed around 5 percent for the same period.

Preliminary projections from Maryland's 1990 testing cycle show that 4 percent of Maryland's pathologists will fail their second test and have to undergo retraining.

These test results show that there is a continuing need for cytopathology proficiency testing in Maryland and New York because 4 to 5 percent of each State's cytopathologists were found to need retraining each time a proficiency test cycle is conducted. I have no doubt that similar numbers of cytology laboratory personnel would also fail in the remaining 48 States where proficiency testing programs do not exist. Many of these States are looking to the Federal Government to provide the regulatory and fiscal support needed to implement such programs.

It took Maryland almost two full years to develop and implement an effective proficiency testing program reflecting actual laboratory practice in cytopathology. The technical and operational problems associated with developing and implementing a monolithic national cytopathology proficiency testing program that reflects actual laboratory practice may prove neither practical nor cost-effective. Yet any proficiency testing program for this discipline that does not reflect actual laboratory practice will contribute little toward either improving these laboratories or protecting the public.

I and my department believe that a high-quality, national cytopathology proficiency testing program can be effectively implemented in a timely fashion only by developing and accepting State or regional programs, standardized under a Federal regulatory umbrella.

In summation, the data presented in my testimony shows a definite continuing need for cytopathology proficiency testing . However, the technical complexities and fiscal constraints associated with

implementing a single, diagnostically-reliable and legally-defensible nationwide testing program within an acceptable time frame may be impractical.

Therefore, Mr. Chairman, I will conclude by urging that this committee urge the Health Care Financing Administration to make the most effective and efficient use of precious time and scarce health care resources by providing fiscal support in a regulatory framework that will both allow and require States or regions to implement their own proficiency testing programs for cytopathology laboratories.

Mr. Chairman, on behalf of the Maryland State Department of Health and Mental Hygiene, we thank you and the committee for this opportunity to testify on the continuing public need for cytopathology proficiency testing.

Thank you.

[The prepared statement of Dr. DeBoy follows:]

Prepared Statement of Dr. DeBoy

Mr. Chairman and members of the committee, I am John M. DeBoy, Dr.P.H., chief of the Division of Laboratory Licensure, Certification and Training, in the Maryland State Department of Health and Mental Hygiene. I appear before you today to present data that will show a continuing need in this country for proficiency testing programs that will test all cytopathology laboratories, and the pathologists and cytotechnologists, employed in screening and evaluating Papanicolaou smears for cervical cancer.

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In cytopathology the only type of proficiency testing program that can test individuals reliably and fairly is one providing test conditions that closely match a cytopathology laboratory's daily work routine. Maryland developed such a program by requiring that the test materials be actual patient Pap smears, that they be hand-carried to the laboratory and diagnosed on-site, and that the testing be conducted under the supervision of a regulatory official.

In just under 24 months the Maryland State Department of Health and Mental Hygiene, with much help from a panel of expert Maryland cytopathologists and cytotechnologists, designed this type of proficiency testing program, drafted and promulgated necessary regulations, obtained and evaluated patient testing materials, and conducted pilot proficiency tests. Maryland's new regulatory program for cytopathology laboratories was fully implemented as of November 1989; and its first official proficiency testing cytle was begun January 1, 1990.

Mr. Chairman, I will now present some actual cytopathology proficiency test statistics obtained between January and August of 1989, when Maryland conducted its pilot tests of 72 laboratories. Twenty-six percent of these 72 laboratories failed the test. The 19 laboratories that failed accounted for 14 percent of the 1,100,000 Pap smear slides diagnosed in Maryland during 1989. Seventy-nine percent of the laboratories that failed read fewer than 10,000 slides per year; 68 percent read fewer than 5,000 slides per year.

A tally of test results showed that 22.5 percent of 129 pathologists failed, and that 12.3 percent of 106 cytotechnologists failed. Only 39 percent of pathologists who did not employ cytotechnologists passed; while 88.6 percent of pathologists who employed cytotechnologists passed. This represents a 50 percent higher failure rate among cytotechnologists who did not employ a cytotechnologist.

This data showed that the smaller laboratories, especially those consisting of a single cytotechnologist, are most likely to fail proficiency testing. This means that any cytology proficiency testing program must make a special effort to identify and routinely test these smaller laboratories.

A review of individual test-slide diagnoses made by the cytotechnologists showed that 5 percent of all diagnoses were significant undercalls or false negatives. Just under 1 percent were significant overcalls or false positives. Persons taking a proficiency test can be expected to perform at their best. When cytopathologists diagnose a 5 percent false negative rate in proficiency tests, it's fair to suggest that the false negative rate in routine practice may be substantially higher.

In 1971–72 New York State's pilot test failed 46 percent of its laboratories. In 1989 Maryland's pilot test failed 26 percent of its laboratories. The proportion of cytopathologists who failed initial tests during New York's 1972–73 testing cycle was 33 percent. In Maryland in 1989 it was 22.5 percent. The past 18 years were heavily regulated ones for medical laboratories in this country, but this seems to have had little effect on many individuals' personal proficiency in diagnosing Pap smears. In New York the failure rate for a cycle's initial test has remained around 20 percent for the last ten years. The percentage of cytopathologists in New York who fail a second test and require retraining has stayed around 5 percent over this same period. Preliminary projections from Maryland's 1990 testing cycle show that 4 percent of Maryland's pathologists will fail their second test and have to undergo retraining.

These test results show that there is a continuing need for cytopathology proficiency testing in Maryland and New York because 4–5 percent of each state's cytopathologists are found to need retraining each time a proficiency test cycle is conducted. I have no doubt that similar numbers of cytology laboratory personnel would also fail in the remaining 48 states where proficiency testing programs do not exist. Many of these states are looking to the Federal Government to provide the regulatory and fiscal support needed to implement such programs.

It took Maryland almost two full years to develop and implement an effective proficiency testing program reflecting actual laboratory practice in cytopathology. The technical and operational problems associated with developing and implementing a monolithic, national cytopathology proficiency testing program that reflects actual laboratory practice may prove neither practical nor cost effective. Yet any proficiency testing program for this discipline that does not reflect actual laboratory practice will contribute little toward either improving these laboratories or protecting the public. I and my department believe that a high-quality, national cytopathology proficiency testing program can be effectively implemented in a timely fashion only by developing and accepting state or regional programs, standardized under a federal regulatory umbrella.

In summation the data presented in my testimony shows a definite, continuing need for cytopathology proficiency testing. However, the technical complexities and fiscal constraints associated with implementing a single, diagnostically reliable and legally defensible, nation-wide testing program within an acceptable timeframe may be impractical.

Therefore, Mr. Chairman, I will conclude by urging that this committee request the Health Care Financing Administration to make the most effective and efficient use of precious time and scarce healthcare resources by providing fiscal support and a regulatory framework that will both allow and require states or regions to implement their own proficiency testing programs for cytopathology laboratories.

Mr. Chairman, on behalf of the Maryland State Department of Health and Mental Hygiene I thank you and the Committee for this opportunity to testify on the continuing public need for cytopathology proficiency testing.

Senator ADAMS. Thank you, Dr. DeBoy.

Senator Cohen.

Senator COHEN. Thank you, Mr. Chairman.

Ms. Ashton, could I focus on an issue that you have raised. You have indicated that because of the changes that have been made, or the enforcement that hopefully will be applied, that some of the costs are going to go up for the reading of the tests; there are going to be delays, there are going to be higher costs, and there will be fewer slides read.

In your judgment, will the delays increase costs and the reduction in number of slides read increase or pose a greater threat to the health of women, for example?

Ms. ASHTON. I think there are definitely some trade-offs. In a general answer, the increased delays will not significantly increase

the risk to women because the disease that we are dealing with is a relatively slow-growing disease. I don't submit to the argument that if a Pap smear result is not returned in 24 hours' time that the woman is going to unduly suffer. Now, 6-month delays, 9-month delays, we certainly would not like to see.

The increased cost—and I should take a step back and say that it is appropriate that Pap smears cost more than they have. They have been severely underpriced by the laboratory industry for many, many years, and we testified about this 2 years ago.

Senator COHEN. Well, as a matter of fact, I believe you testified before the committee—and if the other members here do not remember this—that there were some labs that were charging about 80 cents a slide, as I recall, and by the time it went through the physician's office, it was up to as high as $40 or $33 per slide.

Senator ADAMS. Thirty-three dollars.

Senator COHEN. One of the reasons that we recommended direct billing, which unfortunately did not come out of the legislation, but that is an example of where there were rather dramatically increased costs.

I think we have to take this into account because we are about to debate a Pepper Commission Report, national health care legislation that has been pending now for some time, as we see increased costs being added to our health care system, and now we have a situation where we may indeed increase the costs even more in order to ensure the safety of the people who are providing the tests.

Ms. ASHTON. My feeling on that is the increased cost hopefully will not be reflected in increased cost to the patient—I think that's naive, isn't it?

Senator COHEN. I think that is naive, yes.

Ms. ASHTON. We are exceedingly supportive of direct billing, as you know. We feel that the majority of the fees for Pap smears have not been getting to the laboratories where it is desperately needed to pay the salaries of cytotechnologists and to pay for the cost of quality. It has been getting into the pockets of the people who obtain the smears. And we are exceedingly supportive and would encourage you in any way to reintroduce or amend the legislation to incorporate a direct billing provision.

Senator COHEN. Did you see any improvement in the conditions of the labs from the first year to the second year—in the big labs versus small labs—did you see a distinction there?

Ms. ASHTON. We have been into two laboratories in the second year of the contract that were examined in the first year of the contract, and yes, there was improvement in their operation.

We have been visiting a different type of lab from the first year to the second year, in many instances. The first year, we did go into the very largest labs performing Pap smear testing in this country. In the second year of the contract, we have been into more of the smaller labs, and into two hospital laboratories. I wish I could say the performance has been better in the labs that we have looked at in the second year, but I cannot say that. It is a different type of lab.

Senator COHEN. Dr. DeBoy, I have a couple of questions, if I might, for you. I think you have indicated that proficiency testing

tends to measure the best performance of the lab or the technician; that the error on a daily basis might be much higher. Is that not the case?

Dr. DEBOY. When I say "much higher", it may be up as high as 7 percent. Ninety-five percent of Pap smears are basically negative. That remaining 5 percent, 7 percent of those might be undercalled or false-negatives.

Senator COHEN. So you go from 5 percent to an increase of how much?

Dr. DEBOY. Maybe three out of a thousand slides might be undercalled.

Senator COHEN. OK. Could you tell me about this issue of requiring on-site testing, or can you achieve the same results with an off-site proficiency test? I raise this issue because of the question that there have been a number of professional organizations who say that the proposed regulation that would require at least two annual tests, one on-site with the specimen under glass, is simply not feasible, and there is some suspicion that perhaps the most rigid standard is being proposed in order to weaken the ultimate outcome.

Dr. DEBOY. I believe it is feasible. The question comes up as to whether it is feasible for one national group to prepare and obtain sufficient glass slides to cover the entire country. That's very difficult. If you could break it down at the State or regional level, it becomes somewhat easier.

Senator COHEN. So it is feasible to have that if you can break it down.

Do you have any advice for the States or organizations that are interested in developing their own proficiency testing?

Dr. DEBOY. The only advice I have at this point is that it is a difficult and complex process. It took Maryland approximately 1 year just to come to a consensus with its experts as to what the diagnostic categories and the terminology should be in these tests. I would suggest that where other States start from scratch on this, that they look at Maryland's already and consider adopting what we have already developed.

Senator COHEN. Can I ask what happens when a pathologist or a cytotechnologist fails his or her proficiency test exam. Do you go back and re-screen prior tests of that particular individual?

Dr. DEBOY. At this point in Maryland, we have not required that.

Senator COHEN. Is that not a good idea?

Dr. DEBOY. It is a good idea, yes.

Senator COHEN. And the reason you have not required is because it is too expensive?

Dr. DEBOY. I have not looked into the cost of that, quite frankly. The look-behind study is a good one. Up to this point, Maryland has not done this, the State Health Department in Maryland, because we have not had cytotechnologists on staff that could go out and do this. The one laboratory in Maryland referred to which was going back and checking, and the Medicare certification has been taken away from them over the last 2 months, that laboratory was in fact suggested by the State Health Department to the regional office in Philadelphia that they take a look at that laboratory be-

cause we did not have the resources at the time to do what they in fact did.

Senator COHEN. Mr. Chairman, I want to take this occasion to thank both Ms. Ashton and Dr. DeBoy, and you and Senator Mikulski for calling this hearing. It has been very important. And I want to commend Ms. Ashton for the work that she has done.

I don't know where we go from here in terms of who is going to follow up in the wake of the completion of your particular contract or study, but that is a very important question for us to try and answer.

Senator ADAMS. Thank you, Senator Cohen.

Senator Mikulski.

Senator MIKULSKI. Thank you.

I'd like to really welcome both of the panelists. First, to you, Ms. Ashton, and the professional association that you represent. There was a point in my life when I considered being a medical technologist. I was a freshman at Mount Saint Agnes College, which had a whole specialty in medical technology, a four-year program with a internship, and I'll be talking with you about it. I think you have been doing an outstanding job, and your professional association has been invaluable in helping us formulate our views on this.

And Dr. DeBoy, I know it was Delegate Joan Pitkin who introduced the legislation, our Governor Don Schaefer and our Secretary of Health, Adele Wilzack, who really just moved it. We have a Governor who says "Do it now", and we are pleased that he was as committed to these social issues as he is to light-rail, and in fact, this has moved better than light-rail.

So we thank you for taking this on, because we began in Maryland about the same time we were beginning nationally, and here we have a Maryland program that is up and operating.

Ms. Ashton, you were really part of this national survey, and you talked about the laboratory that was closed. Was that in Rockville?

Ms. ASHTON. Yes.

Senator MIKULSKI. Could you tell the committee what you found in Rockville, MD and what were the consequences of your investigation; and is this the one where you closed down—essentially, it was a laboratory Superfund site?

Ms. ASHTON. This laboratory has just recently been terminated from the Medicare program. I did not personally participate in the survey of this laboratory. If you will give me a chance, I will get out my notes on some of the findings.

Basically, the findings in this laboratory were that the personnel who were performing Pap smear examinations in the laboratory were not felt to be qualified, did not have specific training in cytology to do the surveys in the laboratory. The lab was supervised by a cytotechnologist who had been in the field for a number of years, and was directed by a pathologist who provided direction, possibly on a part-time basis—this was not his full-time responsibility—in this laboratory. We found very significant deficiencies in all of the conditions of participation for Medicare in which we looked, which were the laboratory director's supervision, technical personnel, management, and quality control.

There were a number of case discrepancies identified in the laboratory, and I have not seen the laboratory's response, its plan of correction to tell me what they have done about those cases.

Senator MIKULSKI. So they have not been closed; they have just been separated from reimbursement.

Ms. ASHTON. They have been terminated from the Medicare proceedings, and it is my understanding that the CLIA notice of loss of license is being prepared.

Senator MIKULSKI. What does "loss of license" mean—that they would be closed, or that they are not going to be reimbursed?

Ms. ASHTON. They will not be able to accept specimens in interstate commerce. And it is also my understanding that the majority of their specimens came from the District, the State of Virginia, and Maryland as well.

Senator MIKULSKI. Dr. DeBoy, did you want to comment on this situation?

Dr. DEBOY. At this point, based on the fact of having received a copy of the deficiencies from Federal review, Maryland is taking action now revoke their permit to operate.

Senator MIKULSKI. So this is the way we would hope in some ways the bill would work. In your survey, you were essentially performing the kind of function that we would if we were enforcing the bill—am I correct in that?

Ms. ASHTON. Yes.

Senator MIKULSKI. I don't want to use "dry run", but it was a "cameo", if you will, of how the bill would work—because you see, my concern is just because a lab doesn't get reimbursed does not mean that we are protecting the citizens in the community.

Ms. ASHTON. That's a grave concern of ours as well.

Senator MIKULSKI. So that termination of reimbursement—but then you notify the appropriate authorities, that is, HCFA, and the results of the survey came to a State that also had a law. Do most States have a laboratory proficiency bill, that when the Federal law is implemented, these kinds of notices, particularly in primarily rural States, as you have indicated, that might have very small resources——

Mr. DEBOY. Most States in the country do not have laboratory laws. Only a minority of States——

Senator MIKULSKI. Most State don't have what, Doctor?

Dr. DEBOY. Do not have laws that regulate laboratories—State laws. So in many States, Medicare, HCFA is the only regulating body over the laboratories.

Senator MIKULSKI. And in our law, the only thing that would happen is termination of reimbursement, not the closing of the lab.

Ms. ASHTON. In which law—I am sorry, Senator Mikulski.

Senator MIKULSKI. The CLIA 1988.

Ms. ASHTON. No. I think——

Senator MIKULSKI. Ms. Ashton, thank you. Essentially, I am just relieved. If nothing else came out of the August 5th reg than HCFA's follow-up to employ this survey, the Pitkin-Schaefer-Wilzack-DeBoy action, we have at least helped the people of Maryland to be safer.

But one of the things that we talk about in the bill is proficiency testing of cytotechnologists. I am, of course, concerned about work

force availability, work force reliability, and work force respect. Could you tell us what are the educational requirements to be a professionally-certified cytologist, to be a member of your association, and what are the salary ranges for a cytologist?

Ms. ASHTON. The educational requirements have changed dramatically from the Seventies to the present day, and the regulations do not actually reflect the changes that have come about in the educational resources.

Basically, a cytotechnologist must have 2 years of college preparatory work including training in the biological sciences, chemistry, and then must spend a year after their 2 years of college in an accredited training program specifically for cytotechnology——

Senator MIKULSKI. Excuse me, Ms. Ashton. Are you talking about someone could do this with an associate of arts degree, plus 1 year, or are you talking about a baccalaureate program, plus 1 year?

Ms. ASHTON. Well, what we would consider to be the gold standard is the baccalaureate degree, which may include the year's training in cytotechnology, or a year's training following the baccalaureate degree, and then professional certification in the field. This is what I did. This is then the requirement since 1988, that a baccalaureate degree is required to be a cytotechnologist. Prior to that it was the requirement for an associate's degree, or 2 years of college and a year's specialty training in cytotechnology.

Senator MIKULSKI. I know my time is up, but could you just for the record tell us what this very demanding and technical field pays—a field on which our lives are at stake?

Ms. ASHTON. Well, when I talked to you 2 years ago, I think I probably told you that cytotechnologists were making anywhere from $12,000 to $20,000. With the increased regulation, New York State having already instituted workload guidelines, and with the relatively few numbers of cytotechs that are practicing in this country, the salaries now have increased to a range of $20,000 to $28,000.

Senator MIKULSKI. And my last question: How many cytologists are practicing in this country?

Ms. ASHTON. We estimate there are about 5,000.

Senator MIKULSKI. Mr. Chairman, we are going to have a work force shortage not only because of the demands we are placing here, but really the expectations.

Do you feel that there is a work force/cytologist shortage?

Ms. ASHTON. There definitely is a shortage. The study conducted by the American Society of Clinical Pathologists last summer indicated that there are 13 percent vacancies at the staff cytotechnologist level in laboratories throughout this country.

We are attempting to address that issue, with your help. In limiting the workload of cytotechnologists and with increased salaries, we are finding that more people are becoming interested in going into the field and that we are beginning to see increases in enrollment in our training programs.

I very frankly, a number of years ago, would not have wanted to recruit people into cytotechnology when I knew that after 4 years of education they were going to receive $15,000, let's say, and be on

an assembly line, production. I think we see that changing, and a large part of that is due to your work.

Senator MIKULSKI. Well, Mr. Chairman, I know my time is up. This is really part of our work force shortage concerns, both in x-ray technology and in laboratory technology. And Mr. Chairman, it is my concern that here we have associate of arts programs, we have baccalaureate programs, but then we have schools, Mr. Chairman—I get ads at my house all the time: "Be a lab tech in 6 weeks". We see what Ms. Ashton in her career does for cytology, even for the tests that are not quite slide-based, maybe diabetes.

I don't know anybody who can be fit for duty in this for 6 weeks. It takes longer. We ought to at least have people training as long as it takes to produce a Marine as it does a laboratory tech.

Senator ADAMS. I agree with you, Senator Mikulski, and it is of great concern to us. We learned the actual system being used, the physical examination of slides by individuals looking, eyeballing these slides and making these determinations, and we just feel there has to be a quality-type person there.

I want to follow up on the thing that we just started with Dr. DeBoy and yourself, because you are a system of checking what we hope will be the system that will be used for checking in the future. You are sort of a preliminary survey.

I want to ask you directly—in Exhibit 3 of your testimony—and we do not yet in the State of Washington a law such as you have, Dr. DeBoy, and I am going to start working to see if we can't get one of those, because this cutting off just of compensation, I don't think answers it. Ms. Ashton, you indicate as Numbers 27 and 28 in your Exhibit 4 that two laboratories in the State of Washington—Our Lady of Lourdes Hospital in Pasco, and the Northwest Cytolab in Seattle—have a whole series of deficiencies.

I have looked over to the deficiency list exhibit, and on one it lists "77" and "87" as deficiencies, and "77" says "specimen records", and "87" says "quality control, general".

Now that is a real red flag to me, and I'd like to have you tell me a little bit about what you found in these two laboratories or what those symbols mean if you were not the one who directly examined them, because these laboratories have obviously got a series of deficiencies, and I assume, since we don't have a law in the State, they are still operating.

Ms. ASHTON. Our Lady of Lourdes Hospital did have condition-level deficiencies. It has corrected those deficiencies. The State surveyors from Washington have been back into the hospital laboratory, and it has corrected those deficiencies and is considered to be meeting the requirements.

It is a little bit hard for me to tell you exactly what the specific findings were in the laboratory. I did not perform that survey. But you did indicate that "77" refers to "specimen records", patient records. Frequently, that citation is used when the laboratory does not maintain an exact copy of the report that went out to the patient's physician. I am sorry, but I can provide you with more information on that——

Senator ADAMS. Would you please provide me with that at a later time?

Ms. ASHTON. Yes.

Senator ADAMS. And the Northwest Cytolab, I notice a series of those, but the one that bothers me is "95", where it says "quality control and methodologies". What does that mean is going on there?

Ms. ASHTON. What we indicated in this laboratory was that their quality control program was not adequate to provide a daily check on their technologists working in the laboratory.

This was a laboratory that had two supervisory, trained cytotechnologists and one who had less than 4 years' experience—I stand corrected—they all had 4 years' experience. So they are not required to perform a 10 percent re-screen of the specimens that those techs have interpreted to be benign as part of the regulations.

In the old regulations, in the 1967 law, people who had 4 years' experience did not have to have their work reviewed. We felt that the other things that they were doing in that laboratory to check on the accuracy of their reports may not have been adequate to give them a real handle on how well they were performing.

They were generally a very good laboratory. I guess sometimes we are pretty tough on the laboratories, and I think you need to know that each one of these so-called E-tag numbers is not of equal significance. There are certain things that are much more important than others.

Senator ADAMS. I understand that, and the reason that I asked the question goes to the same thing that Senator Mikulski had commented on earlier, and what both of us found as we entered this and were trying to draft CLIA. We were getting the testimony from the patients in our areas and from some of the doctors—that more and more physicians are relying upon tests. This is becoming a technical world of making value judgments as to the health of individuals, and in many cases—and that is why we focused on the Pap smear—a life or death decision, based upon tests that are out there, being performed by people that, as we went out and started to look at them, we found they were all the way from people just dropping things in the mail and getting them back, to laboratories they had formed themselves, some of the physicians, to some of the very small laboratories. And one of the things that I am concerned about—and I hope that some of the HCFA people are still here—is that we use the system for the 12,000, but that there be a coordinated effort with the States for these smaller laboratories. In the West in particular and in any agricultural or rural State, you will have a number of small laboratories available. That's why I asked the question about the 300,000 or 600,000. A person is just as dead from receiving the wrong information from a very small lab as from a Pap mill. And we don't want to create a lot of extra work for people in the sense of an extra bureaucracy, but we want a system like you have set up where these laboratories are not only looked at for their quality, their review process, but that there is some screening, and if it is shown that they are not performing, that there is an ability to close the lab—the fact that its money is shut off from one area is not sufficient.

So on behalf of the whole committee, I want to thank both of you for giving us a small picture of how the enforcement and implementation might work, with a statement to those in the audience

still left from the Federal area that this is what the committee wants to have happen. We are not interested in writing a lot of words. We want to have some people in the field who are giving some assurance to the doctors and to the patients that the slides that they are getting back are reliable. And you have shown some of the sides of the picture, and we want it done. We will have another hearing, and if we find at the next hearing that it has not been done, then that blackboard that I referred to as being clean will be very dirty indeed.

Thank you both very much.

I want to thank all of the other panelists who appeared. It is very important, and we appreciate your time.

These committees will stand adjourned, and the hearing is completed.

[Whereupon, at 12:40 p.m., the joint hearing was concluded.]

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